AD-A128 233 THE COMMERCIALIZATION OF NEW TECHNOLOGIES TRANSFER FROM LABORATORY TO FIRM(U) ARMY MILITARY PERSONNEL CENTER ALEXANDRIA VA H D JONES 09 MAY 83 1/2

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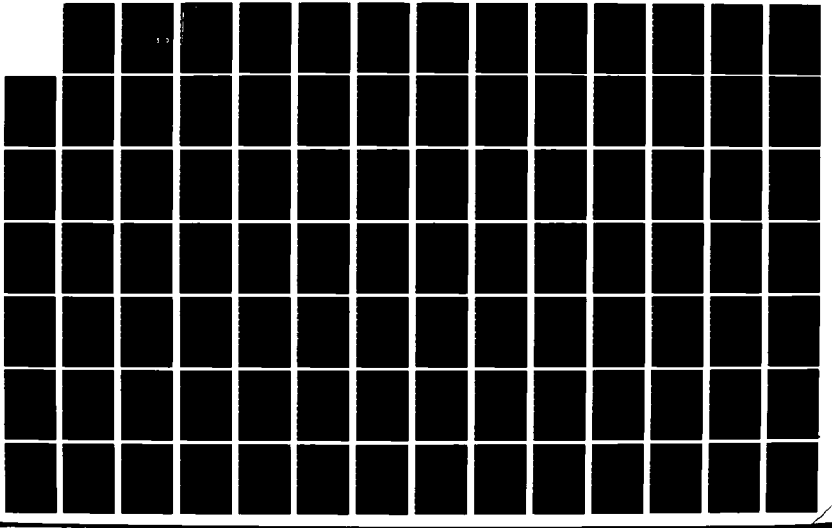

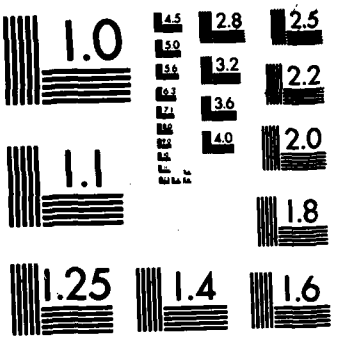

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SECURITY CLASSIFICATION OF THIS PAGE (When Date Entered)

REPORT DOCUMENTATION PAGE

READ INSTRUCTIONS BEFORE COMPLETING FORM

(2)

1. REPORT NUMBER

2. GOVT ACCESSION NO. AD-A128233

3. RECIPIENT'S CATALOG NUMBER

4. TITLE (and Subtitle)
The Commercialization of New Technologies: Transfer from Laboratory to Firm.

5. TYPE OF REPORT & PERIOD COVERED
Final Report, 5 May 83

6. PERFORMING ORG. REPORT NUMBER

7. AUTHOR(s)
Harvey D. Jones Jr.

8. CONTRACT OR GRANT NUMBER(s)

9. PERFORMING ORGANIZATION NAME AND ADDRESS
Student, HQ DA, MILPERCEN (DAPC-CIT-E)
200 Stovall St.
Alexandria, VA 22332

10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS

11. CONTROLLING OFFICE NAME AND ADDRESS
HQ DA, MILPERCEN, ATTN: DAPC-CIT-E
200 Stovall St.
Alexandria, VA 22332

12. REPORT DATE
9 May 83

13. NUMBER OF PAGES
135

14. MONITORING AGENCY NAME & ADDRESS(if different from Controlling Office)

15. SECURITY CLASS. (of this report)
Unclassified

15a. DECLASSIFICATION/DOWNGRADING SCHEDULE

AD A128233

16. DISTRIBUTION STATEMENT (of this Report)

Approved for ~~public public~~ public release; distribution unlimited.

DTIC ELECTE S D MAY 17 1983 B

17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)

see 16.

18. SUPPLEMENTARY NOTES

Thesis submitted to the ~~Slac~~ Sloan School of Management, Massachusetts Institute of Technology in partial fulfillment of the requirement for the degree of Master of Science in Management.

19. KEY WORDS (Continue on reverse side if necessary and identify by block number)

Technology Transfer;
The Innovation Process;
The Commercialization of New Technologies;
Technology Diffusion.

20. ABSTRACT (Continue on reverse side if necessary and identify by block number)

(on reverse)

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SECURITY CLASSIFICATION OF THIS PAGE (When Date Entered)

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The purpose of this thesis is, therefore, to conduct field research on those factors that impact the successful transfer of technologies from university R&D labs to the market. In order to narrow the scope and focus of the investigation, the~~se~~ specific issue of technology maturity and its impact on the innovation ~~proce~~ process is examined.

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THE COMMERCIALIZATION OF NEW TECHNOLOGIES: TRANSFER FROM LABORATORY TO FIRM

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THE COMMERCIALIZATION OF NEW TECHNOLOGIES:

TRANSFER FROM LABORATORY TO FIRM

by

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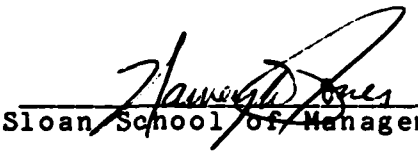
B.S., United States Military Academy
(1974)

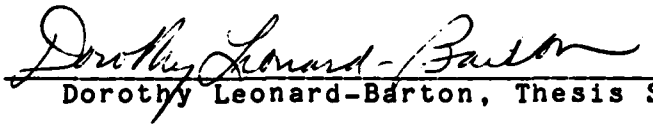
Submitted to the Sloan School of Management
in Partial Fulfillment of the
Requirements for the Degree of
Master of Science in Management

at the

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

May 1983

Signature of Author: 
Alfred P. Sloan School of Management, 1 May 1983

Certified by: 
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THE COMMERCIALIZATION OF NEW TECHNOLOGIES:

TRANSFER FROM LABORATORY TO FIRM

by

Harvey D. Jones

Submitted to the Sloan School of Management
on 1 May 1983 in partial fulfillment of the
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ABSTRACT

Universities have commonly been considered a source of new technologies and new products, yet recent studies have presented evidence that many potential innovations that originate in academic institutions go unexploited despite the desire of the inventors to commercialize them and despite the needs of many businesses to innovate. A number of factors that impact the successful transfer of technologies from universities to new and existing firms have been identified in the literature, but many of these observations are based on folklore, personal experiences, and generalizations. Empirically based field studies designed to provide a greater depth of understanding of the process of technology transfer and the commercialization of new technologies are somewhat limited.

The purpose of this thesis is, therefore, to conduct field research on those factors that impact the successful transfer of technologies from university R&D labs to the market. In order to narrow the scope and focus of the investigation, the specific issue of technology maturity and its impact on the innovation process is examined.

Five cases involving actual transfers of medical technologies from universities into firms in the greater Boston area were developed from a series of structured interviews, analyzed with respect to the issue of technology maturity, and used as the basis for drawing specific conclusions about the interorganizational transfer of technologies.

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Title: Assistant Professor of Management

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CHAPTER I: INTRODUCTION

During this period in U.S. history when many are of the opinion that American productivity and resourcefulness are on the decline and are being overcome by foreign competition, it would not be unreasonable to think that these declining businesses and those that want to remain viable are using all the means and resources at their disposal to generate new product and process ideas and to identify new technological opportunities (Hayes & Abernathy,1982; Lewis, 1982).

One such potentially significant source of innovation ideas lies in colleges, universities, and other academic institutions. These organizations are oriented towards education, the pursuit of fundamental scientific and engineering knowledge, the free exchange of information, and intellectual independence. With many of the top minds in the world performing and directing research and investigations into problems, issues, and new endeavors that have potentially beneficial social, economic, and industrial applications, university R&D laboratories would seem to offer businesses significant advantages for increasing their ties and interactions. Such links could complement and enhance industrial research efforts with state-of-the-art techniques and allow businesses to maintain competitiveness in current product lines and to expand into new products based on new technological

developments and university originated research breakthroughs (Prager & Omenn, 1980).

Past and recent studies of sources of innovation and the extent to which commercializable ideas originate from academic sources, however, present contradictory evidence regarding the expectations expressed above. Although many potentially exploitable ideas do originate in university R&D facilities, many more never reach the market as commercial product or process innovations.

Roberts & Peters (1969) conducted a study involving 299 university scientists from the MIT Lincoln and Instrumentation Laboratories to determine the extent to which such potentially commercializable ideas are unexploited. Focusing on ideas that fall outside the scope and interest of the parent laboratores, they learned that:

- 47 percent of these researchers claimed such ideas;
- 3.5 ideas were generated per claimant;
- 33 percent of the claimants attempted to commercialize their ideas; and
- 67 percent of them did not do anything.

Continuing in this line of research, they (Roberts & Peters, 1981) published the findings from a similar study of 66 MIT faculty members and learned that:

- 70 percent of them had commercializable ideas;
- 40 percent had multiple ideas; but
- 47 percent of these potential innovations were again unexploited.

Marquis (1969) & Myers and Gibbons & Johnston (1974) analyzed and studied over 500 innovations in 121 companies and 30 innovations involving 887 items of information, respectively. They found that most f[illegible] rely primarily on the knowledge and creativity of thei[illegible]n R&D personnel to generate new ideas and to solve inn[illegible]on problems and seldom go to outside sources for this information. Approximately 67 percent of the innovation ideas originated from sources inside the firms and the remaining, from external sources.

With respect to using universities as sources of technological knowledge and information, only about 7 percent of the transfer situations investigated by Gibbons & Johnston involved them.

In addition to the high percentage of non-utilized technologies and ideas originating in universities, evidence has also been presented that the likelihood of technical completion and successful commercialization of technologies that are transferred is rather low. Only about half of the internally generated new product ideas identified by an innovating organization ever reach technical completion and only 20-30 percent achieve commercial success (Urban & Hauser, 1980, pp. 53-54). The probabilities are expected to be even much lower for ideas from outside sources.

What this evidence indicates is that there are significant underlying barriers inhibiting the transfer of

technologies and ideas from universities to industry. The obvious question that comes to mind is, why do these barriers exist? What are the factors impacting increased university-industry technology transfer interactions? Why do firms not take advantage of university resources and talents to a greater extent?

In order to answer these types of questions, this thesis has been structured to conduct field research, develop cases, and investigate actual technology transfer situations involving universities and firms in the greater Boston area.

Specifically, the investigation focuses on the issue of technology maturity. Because university researchers generally focus on basic research without having a commercial goal or intent in mind, they are usually interested in only developing a technology, idea, or concept just far enough down the road to commercialization to answer the fundamental questions involved. This means that at the time of technology transfer from the university to a firm, the potential innovation is not ready for immediate market introduction. A gap exists, which is a measure of technology maturity, that reflects the amount of additional research and development the firm must perform before the new product or process is ready for commercialization. For this reason, the final commercial product is seldom the same as the university prototype. The larger the gap, the less mature is the technology and

the less likely is the firm to attempt to transfer and commercialize it.

The specific technology transfer model upon which this thesis investigation is based involves the commercialization of medical technologies originating in university laboratories where the initial conception of an exploitable idea and the recognition of a need or technological opportunity occurred. Five technology transfer cases were developed from a series of structured interviews with the key people involved with the innovations and were analyzed with respect to the technology maturity issue. These case are identified in Table 1.

The case write-ups, analyses, and conclusions are included in the remainder of the thesis following a literature review of the role of technology in the innovation process and generally accepted factors that impact the successful interorganizational transfer of technologies.

Table 1: Identification of Cases

Case	University	Firm	Persons Interviewed
1-Bedside Arrhythmia Monitor	MIT	Life Line Systems, Inc.	Professor, MIT; Engineer, firm.
2-Blood Rejuvenation Solution	Boston University	PIPA Lab, Inc	Professor, BU; President, firm.
3-Implantable Drug Infusion Pump	University of Minnesota	Infusaid, Inc	Inventor, Univ.; President, firm; 2 Engineers, firm.
4-The Reach Toothbrush	Tufts University	DuPont and Johnson & Johnson	Professor, Tufts; Research Assoc & Clinician, firms.
5-Viral Inactivation Process	Confid.	Confid.	Inventor, MIT; Engineer, firm.

Note: The names of all people included in the cases have been disguised. Additionally, due to the sensitive nature of case 5, the names of the university and firm involved are confidential and the case name has been disguised.

CHAPTER II: METHODOLOGY

The objective of this thesis project is to conduct field reseach on factors that impact the successful transfer of new medical products into existing or new firms. It is based on:

- data from a series of structured interviews conducted with persons connected with a number of technology transfer situations involving local university R&D facilities and local medical firms;
- the analysis and examination of one specific issue across all the cases developed from the research data.

The approach taken to accomplish this objective followed the steps outlined below:

- identify usable cases,
- develop questionnaire,
- conduct interviews,
- write cases,
- conduct literature review, and
- analyze and discuss results.

Since the basis for investigating those factors that impact the successful transfer of medical technologies from universities is the analysis of actual transfer cases, the initial requirement in the conduct of the thesis project was to identify potential cases. The members of the project searched for and canvassed a number of university and industry contacts to generate cases and to obtain their cooperation and willingness to participate.

We found that the number of usable transfer situations involving university generated medical technologies was somewhat limited. Real transfer situations that fit the

model being investigated were hard to find and when they were, either one of the parties involved did not want to be interviewed or one of them could not recall or disclose certain facts and details about the innovation. Appendix A provides a listing of the transfer situations that were identified by the project members but were not used for various reasons. It also indicates those that were developed into usable cases either for this thesis or the thesis of another project member.

While the list of potential cases was being compiled, a structured questionnaire was prepared by the thesis project team members. The questions were designed to address a number of specific issues which included the following:

- product design,
- managerial roles,
- cultural/organizational gaps,
- technology acquisition strategies of the firm,
- contractual arrangements,
- nature of the recipient firm, and
- government regulations.

The questions were also intended to provide a common framework and information base upon which the project members could extract the information they needed to write their individual theses.

Based on this questionnaire (see Appendix B), and the resulting interviews, the remainder of the steps identified in the methodology were implemented.

CHAPTER III:

THE ROLE OF TECHNOLOGY TRANSFER IN THE INNOVATION PROCESS

DEFINITIONS

For the purposes of this study, innovation is defined as the application of a technology, idea, or concept to a new use or a new user where the application is embodied in a new product or process developed for a specific purpose.

Technology transfer is defined as the diffusion of a technology or technological information from a source to a user, in the same or a different organization, that results in an innovation.

The transfer source is the college, university, or academic institution's R&D facility at which the initial conception of a commercializable idea, the recognition of a need, or the recognition of a technological opportunity occurs.

The user or innovator is the commercial organization that develops, produces, and markets a new product which embodies the technology transferred from the source or that uses the knowledge to solve technical problems related to new product development.

A successful innovation and a successful technology transfer occurs when a new product or process is introduced in the market for the first time. This is also referred to as successful commercialization. A failure occurs when a

potential innovation does not reach the point of market introduction for any reason.

THE INNOVATION MODEL

Many of the general models of the innovation process presented in the literature regard the process as one that occurs in several evolutionary steps spanning several years. The beginning of the process occurs at the time of the first conception of an idea or recognition of an opportunity by an organization and ends when a usable product or process is introduced to the market. The period following this, when the innovation is widely diffused throughout the market, when incremental improvements are made and the firm attempts to maximize its returns is considered the post-innovation period (Gee, 1974; Roberts & Frohman, 1978; Urban & Hauser, 1980; White, 1977).

Between initial conception and first commercial realization, a series of interacting activities, events, and factors impact the success, duration, cost, efficiency, and sequence of the innovation process. The general outline of the steps and stages that must be completed in order to achieve commercialization follows the model presented by Roberts & Frohman (1978) as adopted from the work of Marquis (1969). The sequence of stages is as follows:

- Stage 1: Recognition of opportunity;

- Stage 2: Idea formulation;
- Stage 3: Problem solving;
- Stage 4: Prototype solution;
- Stage 5: Commercial development; and
- Stage 6: Technology utilization and diffusion.

Prior to the first stage, the organization is assumed to have defined its business, technology, and R&D strategies and goals and is aware of its own capabilities, strengths, and weaknesses as well as those of its competitors and other stakeholders in the industry. Given this, it can then pursue projects in the framework of the this model.

Recognition of opportunity involves the conception, recognition, or discovery of an idea, need, or opportunity that can be developed into a new product or process. The sources of such opportunities include the market, the technology environment, and sources within the organization itself. The objective of this stage is to recognize and identify new product and process opportunites.

During the idea formulation stage, technical opportunities recognized from stage 1 are matched with potential or actual market needs and alternative new product ideas are generated that fulfill these needs or exploit the opportunities. These alternatives are evaluated against relevant organizational investment and decision-making criteria and a dominant design concept is accepted and initiated as an innovation project.

Problem solving involves the search of the technology and market environments and use of identified sources and resources to complement and supplement internal R&D activities in order to solve the technical problems inherent in the innovation design concept. If additional R&D is required after the innovation advances to any of the following stages, it returns and the relevant problems are solved.

The prototype solution phase involves adaptive engineering using the technologies and problem solutions from the preceeding stages to perfect a functional prototype of the new product. It is tested for engineering and design efficacy, evaluated in test markets, and strategically analyzed with respect to development and marketing plans. This stage and the preceeding ones are highly dynamic and interactive and will seldomly progess in a linear fashion. Numerous interorganizational, intergroup, interpersonal, and environmental factors impact the progress of the project as it flows through the various stages causing frequent changes and delays. When an acceptable prototype is designed, the innovation then progresses to the fifth stage of its development.

Commercial development involves the refining and focusing of the prototype design based upon the results of the testing and analyses from the preceding stage to meet the needs and requirements of the targeted market segment. The necessary interface with manufacturing, service, sales,

and other stakeholders is initiated or intensified and the organization prepares for the final stage of the innovation process.

Technology utilization and diffusion occurs when the new product or process is sold commercially. Manufacturing start-up, promotions, distribution, and introduction characterize this stage. The technological knowledge embodied in the innovation is applied to either new uses as the firm manages the growth of the product line or is diffused throughout the market and technology environments for use in other innovations projects.

During the post-innovation period, after the new product or process has been successfully launched into the market, its continued growth and development must be monitored and fostered to generate the returns that hopefully will justify the initial investment. The product line is managed throughout its life cycle until disinvested or revitalized and the innovation process is repeated.

THE TECHNOLOGY TRANSFER MODEL

Recalling that the definition of technology transfer is the diffusion of technological knowledge from a source to a user that results in an innovation which embodies the technology, a diagram of the overall relationship with respect to the innovation model is presented in figure 1.

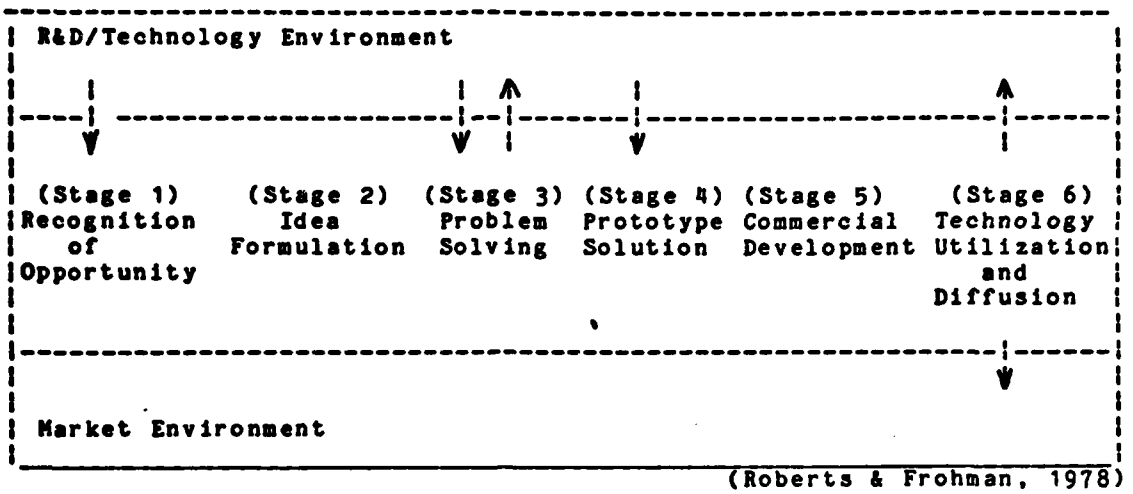
Technology transfer can be considered as a link between the innovating organization and the R&D environment. Although the transfers can originate from sources within the innovating organization, to rely solely on in-house sources denies to the firm the potential benefits and opportunities of available external knowledge and information that could be used to generate new product ideas or to help solve current product development problems (Rothwell,et al., 1974; Roberts & Frohman, 1978). The effective search and use of such potential transfer sources as colleges, universities, medical centers, government R&D facilities, colleagues, users, and other similar sources can be potentially valuable to the innovating organization. As a consequence, the focus of this model is on the interorganizational transfer of technology from sources external to the organization.

According to this model, technology transfer may occur in any one of five different stages of the innovation process as follows:

- in stage 1, it can provide the firm with new ideas or technical opportunites for new products;
- in stage 3, it can provide the firm with problem solving information and techniques to move on-going innovation projects along;
- in stage 3, it can also provide the R&D environment with spin-off information about developments and discoveries made by the innovating organization;
- in stage 4, it can provide the firm with

information needed to develop functional prototpes and achieve technical completion of the innovation;

- in stage 6, it can be used to diffuse technologies throughout the R&D environment for the reasons listed above.



(Roberts & Frohman, 1978)

Figure 1: The Role of Technology Transfer in the Innovation Process.

Note: Interactions between the firm and the market environment do occur, but are not depicted in this diagram in that the focus of this investigation is on the R&D-Firm interface.

To further explain the relationship and role of technology transfer in the innovation process, the technique presented by Gee (1974) is adopted. Gee simply models the process as a time line starting with the conception of an idea and ending with the realization of a new product, process, or technology. By adding the numbers corresponding to the stages of the innovation process from above, the innovation model is presented as in figure 2 below:

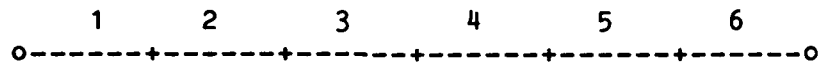


Figure 2: Model of Innovation Process

Although the stages of innovation process are drawn without consideration of the time, effort, costs, or other factors that usually impact the completion of each stage and are also diagrammed in a linear fashion, the intent of the model is not to imply that the process occurs in this way in reality. Its intent is to simply show how and when technology transfer interacts in the development process as the new product progresses down the road towards commercialization.

By designating one such transfer line as the source and the other as the user organization, a clearer depiction of interorganizational technology transfer is presented. In figure 3, a source of a new technology has gone through

a technological innovation process and is transferring the technology involved throughout the R&D environment. The user is the recipient of the transferred information who applies it in any of the following three ways:

(A) to generate new ideas or opportunities that lead to further applications of the technology;

(B) to aid in problem solving with respect to current new product development projects; and/or

(C) to facilitate adaptive engineering of a functional prototype with respect to current projects.

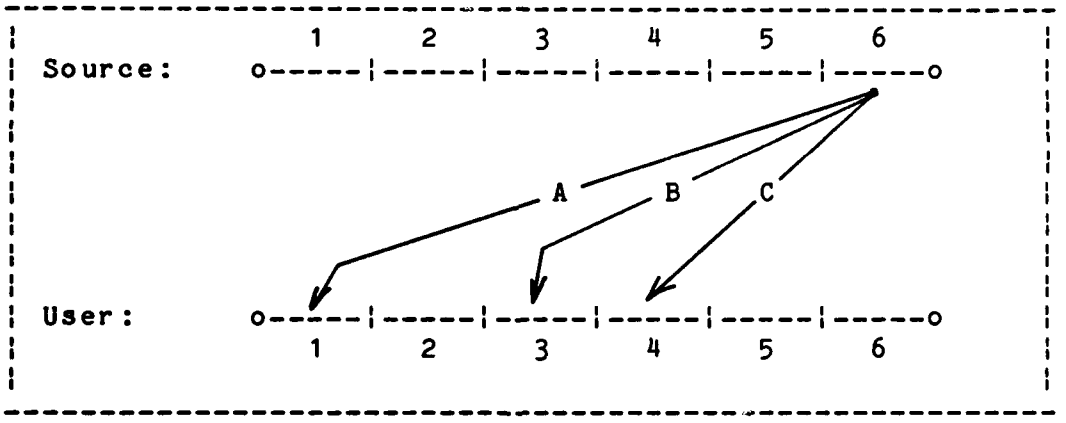


Figure 3: Technology Transfer Model - A.

In figure 4, the source discovers or generates a spin-off technology during the course of its research and development work on another problem. The source in this situation may be either a university R&D lab or a firm's R&D lab. This spin-off is usable and/or commercializable and is transferred to the innovating organization for the same reasons and in a similar fashion as presented in the

situation in figure 3.

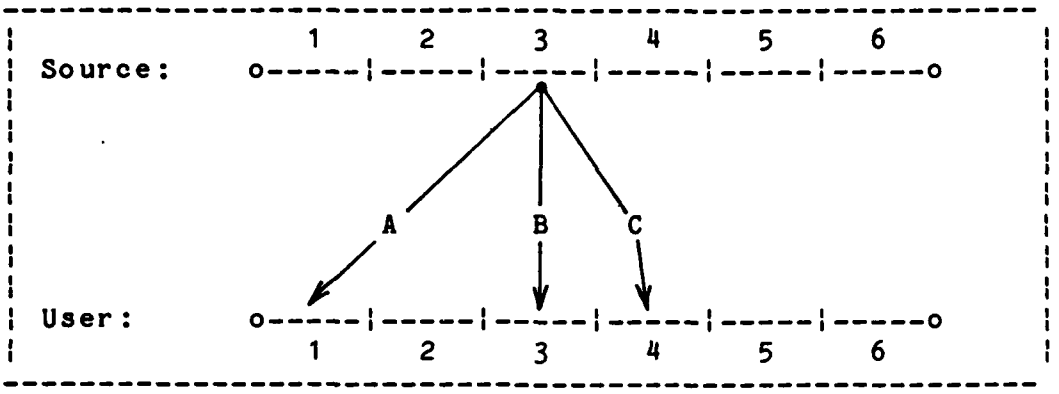


Figure 4: Technology Transfer Model - B

THESIS TRANSFER MODEL

For the purposes of this thesis, the source organizations are university R&D laboratories and the users are commercial firms. The transfers that are being investigated involve university originated technological discoveries or application devices embodying existing or new technologies that have commercial potential.

The universities transfer the technologies to the firms at varying stages of development and maturity and the firms complete any commercialization requirements left undone by the university labs. After the technology has been transferred, the firms must then interact with the R&D environment to get the new products to the market.

THE LIKELIHOOD OF SUCCESSFUL INNOVATION

Mansfield & Wagner (1975) examined industrial product innovations in a number of firms and were able to estimate the average probability of successful innovation as follows:

(1) Probability of technical completion --------- .57
(2) Probability of commercialization, given (1) - .65
(3) Probability of economic success, given (2) -- .74

The probability of successful technology transfer is therefore, 37 percent (.57 x .65) and the overall probability of innovation success is 27 percent (.57 x.65 x.74). Their findings also indicated that the chances of success varied by industry. For example, the probabilities of technical completion ranged from .32 for the drug industry to .73 for electronics (Urban & Hauser, p 53).

For consumer product innovations, Urban & Hauser (1980, p54) estimated the following probabilities:

(1) Probability of successful design ---------- .50
(2) Prob. of successful test market given (1) -- .45
(3) Prob. of market success given (2) ---------- .85
Overall probability of success .19

The significance of these findings is that only about half of the new product opportunites identified by an innovating organization ever reach technical completion. Recalling the stages of the innovation model and the roles of technology transfer in this process, this 50 percent

failure rate is attributable to the inability of the firm to solve technical problems (stage 3) and to develop functional prototypes of the new product concept (stage 4). Both of these stages may involve significant interactions with the R&D environment where technology transfer potentially has the greatest impact on the outcome of the innovation. Therefore, to increase the likelihood of technical completion, stages 3 and 4, one alternative would be to increase the interactions of the firm with the R&D environment and to promote the transfer of technological knowledge and information.

A reasonable conclusion to draw from this observation is that a better understanding of the factors and technology transfer barriers that can facilitate or hinder technical problem solving and prototype solution may lead to higher technology utilization rates.

CHAPTER IV:

FACTORS THAT IMPACT THE SUCCESSFUL TRANSER OF TECHNOLOGY

From the discussion presented in Chapter III, a number of benefits to technology transfer become evident. Improvements in the university-firm transfer process could be used to help shorten the time, effort, and resources expended to achieve realization of a new product or process; to increase the likelihood of technical completion; and consequently, to minimize the risk and uncertainty inherent in many innovation projects. Additionally, improved technology transfer could help to promote the diffusion of technologies to new markets and new users; to generate new ideas or more creative applications of technologies; and to increase the productivity and welfare of the nation as a whole (Gee, 1974; Roberts & Frohman, 1978).

The key to achieving these potential benefits, however, is that the technology transfers must be successful and success is an uncertain and complex goal. The remainder of this chapter presents those factors that can facilitate or hinder technical problem solving, prototype solution, and the successful transfer of technologies from universities to the market.

ORGANIZATIONAL FACTORS

Goal compatability and congruence determine the extent to which technology transfer is likely to happen. Both organizations involved in the transfer must be able to get what they want out of the relationship and work towards common goals and objectives if the transfer is to be successful (Prager & Omenn, 1980; Gartner & Naiman, 1978; Johnson & Tornatzky, 1981).

With respect to the university-firm linkage, academic institutions generally focus on education, fundamental knowledge, intellectual independence, the free exchange of information, the publication of research findings, and the diffusion of new ideas (Prager & Omenn, 1980).

Commercial organizations, on the other hand, usually pursue economic and financial goals and are concerned with profitability, gaining a competitive advantage, establishing proprietary positions through patents, trade-secrets, and reaction time, and generating adequate low risk, quick pay-off returns on investment (Gartner & Naiman, 1978; Marguis, 1969; Von Hippel, 1982).

These differences in goals and orientations often manifest themselves in attitudes, expectations, and perceptions that are themselves, barriers to effective interaction and communications. Many academicians despise the profit orientation of commercial organizations,

distrust the motives of business persons, and often disapprove of the commercial ties of their colleagues with these firms. Many feel that industry sponsored research and development will result in the loss of freedom to decide on their research objectives, fewer publications, and the lowering of research standards and quality (Prager & Omenn, 1980; Gartner & Naiman, 1978).

Many business persons, on the other hand, feel that university research is too basic and theoretical and gives too little thought to applicability. Many are of the opinion that graduates and researchers cannot adjust to the applied nature and focus of commercial R&D, regard themselves as prima donnas, and are of limited benefit to the firm (Prager & Omenn, 1980).

Gartner & Naiman (1978) also found that significant barriers to technology transfer occur more frequently among the interactions between the people directly involved in implementing the transfers than among the policy makers and administrators at the systems levels of the transfer organizations. Such problems result from a lack of coordination and direction in intergroup and interpersonal relationships and are often impacted by the following factors:

- differences in organizational cultures, attitudes, interests, and goals;
- differences in individual skills, reputations, educations, needs, and motivations;

- lack of formal and informal rewards and incentives for personnel involved in the transfers;
- lack of involvement, interest, and support of senior level managers and product champions;
- lack of explicit technology transfer policies within organizations;
- lack of a transfer structure to help bridge the gap between the interacting organizations;
- shortage of effective managers to facilitate cooperation and to overcome identifiable barriers;

(Prager & Omenn, 1980; Gartner & Naiman, 1978; Johnston & Tornatzky, 1981; Rothwell,et al., 1974; Chakrabarti & Rubenstein, 1973; Marquis, 1969).

COMMUNICATIONS FACTORS

Several studies have shown that the quality and effectiveness of communications with sources of information and advice from both outside and inside the innovating organizations are important to successful technology transfer. In fact, Marguis (1969) observed that most major innovations usually originate outside the firm. In-house personnel are usually concerned with short term incremental product improvements, cost reduction, quality control, and other internal needs. This observation reinforces the need to communicate with outside sources of information in order to keep track of technology trends and opportunities.

Successful innovators were found to facilitate effective communications by:

- consulting frequently with organizational colleagues and external consultants, professionals, and peers;
- using gate-keepers to gather and disseminate information from sources outside the innovating organization;
- promoting frequent informal and formal interpersonal relationships, interdepartmental projects, and organizational transfers; and
- minimizing the physical separation of individuals and groups that need to communicate at various stages of the innovation process.

(Allen, 1970; Gartner & Naiman, 1978; Katz, 1982; Marquis,1969; Rothwell, et al., 1974; Von Hippel, 1978).

TECHNOLOGY MATURITY FACTORS

The divergent goals and interests of university researchers from those of industry often result in university originated technologies and application prototypes that are far less developed down the road to commercialization than many potential innovators would like. University researchers usually focus on basic research without having a commercial goal or intent in mind and are consequently, interested in only developing a technology, idea, or concept just far enough to answer the fundamental questions involved. This means that at the time of technology transfer from the university to the firm, the potential innovation is not ready for immediate market introduction. A gap exists, which is a measure of technology maturity, that reflects the amount of additional

research and development the firm must perform before the new product is ready for commercialization. For this reason, the initial commercial model of the new product is seldom the same as the final university prototype or concept (Chakrabarti & Rubenstein,1973; Gartner & Naiman, 1978; Lambright & Teich, 1976).

The more mature the technology, the more likely is the firm to attempt to transfer and commercialize it. If the university only demonstrates concept feasibility of a new technology and does not design, test, and develop a functional prototype, the innovating firm will have to do so after the transfer. The level of maturity, therefore, impacts the riskiness and uncertainty of the venture and the willingness and likelihood of the firm to become involved with the innovation project.

The following maturity factors have been identified as having an impact on the likelihood of successful technology transfer and utilization:

- match between needed and available resources for commercial product development;
- efficiency of in-house R&D capability as reflected by the quality of their work, use of available resources, frequency of prototype problems and changes, and the amount of time to achieve commercialization;
- quality of the transferred information as reflected by the complexity of the technology and the understanding and competence of the innovating organization;
- effectiveness of personnel training, education, development, and retention;

- relationship of the new technology to the firm's current R&D and technology focus;
- urgency of need for the technology;
- timing of the innovation to coincide with user needs and expectations and competitor strategies;
- incorporation of market and user design requirements and features early in the innovation process;

(Chakrabarti & Rubenstein, 1973; Lambright & Teich, 1976; Gibbons & Johnston, 1974; Marquis, 1969; Rothwell, et al., 1974; Urban & Hauser, 1980; Roberts & Frohman, 1978).

CHAPTER V: CASE WRITE-UPS

CASE 1: Bedside Arrhythmia Monitor (BAM)

INVENTOR: MIT (Biomedical Engineering Center for Clinical Instrumentation)

FIRM: Life Lines Systems, Inc.

INTRODUCTION

In 1976-1977, an MIT professor and director of the Harvard/MIT Engineering Center for Clinical Instrumentation, recognized a need for an improved cardiac monitoring device for hospital patients with symptoms of heart diseases. He and a number of graduate students had been working on rhythm analysis systems and applied their knowledge to developing a prototype of a Bedside Arrhythmia Monitoring device. This system was successfully tested at the Beth Israel Hospital in Boston, transferred to a firm in Waltham, Massachusetts, and is due to be introducted commercially in November 1983.

BACKGROUND

Coronary heart disease is estimated to be responsible for more than 600,000 deaths per year in the United States. Of these, about 50-60 percent are sudden and often occur within an hour of heart disease symptoms. The cause of these sudden deaths is primarily due to the chaotic and

non-synchronous electrical activity of the heart. Coordinated and rhymthic pumping is disrupted and the victims die before they can get to a hospital for help. If they could receive such timely medical attention, the mortality rate due to sudden cardiac arrhythmia disorders could be reduced to 15 percent or less.

When a patient is in the hospital, however, and is known to have a history of coronary heart disease, doctors like to be able to monitor heart rhythm activity for several reasons. These are to:

- quantify how much arrhythmia is present which gives a measure of the risk of sudden death. This is usually done during the recovery phase after a heart attack;
- determine if the patient should be treated and if so, how effective the treatment is likely to be. This requires the observing of heart rhythm for a 24 hour period of time;
- find out more about patients who show intermittent symptoms of what might be an arrhythmia disturbance problem, such as fainting, dizzy spells, and strokes;
- monitor patients with pace makers to find out how well they work. This also often requires a long period of heart rhythm monitoring.

A major therapeutic breakthrough in the treatment of heart attack victims occurred in the 1960's. The coronary care unit (CCU) allowed continuous monitoring of patients by nurses trained in the recognition and treatment of heart rhythm disorders. These units detected and provided warning of severe arrhythmias and documented abnormal trends and the effectiveness of therapy, but the problem of

sudden death still persisted for those people who were not in a hospital being monitored when the symptoms occurred. Also, these early CCU's used large oscilloscope displays and heart rate alarms which had some drawbacks. The alarms often falsely reponded to muscle noise and movements of the electrodes and the electrocardiograph (ECG) displays required continuous observation by nurses. Critical cardiac warning signs were, therefore, difficult to detect and were often missed.

Over the past 5-10 years, the use of portable, battery powered tape recorders has become the standard technique for measuring heart rhythms. This technique is widely used for ambulatory patients who simply carry them around while the heart rhythm data is being recorded. It is also used for patients in general medical wards and areas of less intensive supervision that are not accessible to CCU's or other multi-patient monitoring systems.

The problem, based on the inventor's experiences at Beth Israel Hospital, is that about 60 percent of the ECG monitoring is done on patients who are in the hospital but are in these remote, inaccessible areas. The tape recording technique requires 24 hours of data collection and an additional 24 hours of laboratory processing. So, during a 48 hour period, the doctor has no access to the ECG information. This delays diagnosis and treatment, but more importantly, allows potentially serious cardiac disorders to go undetected for almost 2 days.

These problems, of having to monitor a large percentage of patients in remote areas of the hospital inaccessible to CCU's and having delayed access to vital information using the tape recording technique, are what prompted the inventor to develop an improved ECG monitoring system. His current research focus at the Harvard/MIT Biomedical Engineering Center for Clinical Instrumentation was on rhythm analysis and a bedside arrhythmia monitor was a logical application of this work. Such a device was not practical before this time, but became feasible with the application of microprocessor and other available technologies.

PRODUCT TECHNOLOGY

Sometime around 1976-1977, the director of the Biomedical Engineering Center for Clinical Instrumentation (BECCI) and Director of the Biomedical Engineering Division at Beth Israel Hospital, began working on developing an improved arrhythmia monitoring system with the help of a number of MIT graduate students.

What they wanted as the functional outcome of the project was a system that would:

- provide a continuous, single-patient monitoring capability primarily for hospitalized patients who do not require intensive monitoring in cardiac care units;
- be portable, reliable, self-contained, cost

effective, and easy to use;

- perform real-time, heart rhythm analysis and on-demand hard-copy documentation of: ECG readings; episodes of significant heart rhythm disturbances; and trend plot summaries of key physiologic functions such as heart rate or blood pressure as function of time;
- provide real-time display of physiologic trends;
- sound an optional alarm to alert medical personnel of abnormal heart activities.

The key to the development of a functional bedside monitor was in the software. The ECG analysis algorithm was developed at the BECCI and designed to detect and classify cardiac abnormalities. It is written in assembly programming language, runs on an Intel 8080/8085 microprocessor, is self-learning, and is able to adopt to a variety of background noises and rhythms in an unsupervised environment. It requires 32k bytes of read-only memory for program storage and 16k bytes of read-write memory for variables and arrays.

In addition to the microprocessor and memory, other systems hardware includes:

- optically isolated ECG amplifier and filter,
- analog to digital convertors,
- storage oscilloscope (Tektronix 603) used to display trend plots for 15 minute, 1, 3, and 12 hour periods,
- 2 print-head strip chart recorder for real-time ECG documentation and labelling,
- illuminated push-button console, and
- optional hard-copy plotter for trend data.

Most of the hardware was available off-the-shelf except for the ECG amplifier and the keyboard controller which had to be developed at the BECCI. Additionally, the system bus which provides all data, address, and control signals required by memory and the peripherals, was designed in-house. The Intel microprocessor was selected because hardware and software support was available at MIT, it was popular and would facilitate potential industrial interface, and it could be used with a wide range of inexpensive support chips.

The system processes ECG's in several steps. Initially, after the operator enters the patient's identification number, date, and time, the system "learns" the patients normal rhythm pattern over the first 50 heart beats before it begins classifications. This process occurs as follows:

- the ECG signal is amplified, filtered, and digitized;
- wave pattern amplitude and slope tests are conducted and the structure, form, and timing of the waves are identified;
- rhythm events are recognized and classified;
- results are reported as real-time displays or hard-copy plots of ECG's, physiologic trends and histograms and/or an optional alarm is activated.

Before the MIT prototype of the Bedside Arrhythmia Monitor was transferred out of the laboratory to industry, clinical tests were conducted at Beth Israel, a Harvard University teaching hospital, for over 2 years. In

general, these results were considered favorable. Most users, which included cardiologists, physicians, interns, nurses, and technical staff, felt confident about use of the system. Most felt that it reduced the patients stay in the hospital and that its key advantage was the immediately available physiologic trend summaries and hard copy rhythm strips. In all, 565 hours of data and 3576 ECG's were generated by the Bedside Monitor. 73 percent of these ECG classifications were considered correct and 23 percent, incorrect. This level of inaccuracy required the user to verify output with follow-up readings and indicates an area for improvement in the system. The key to functional improvements lies is the software.

THE TRANSFER TO A FIRM

Dr. Rogers, director of the BECCI, realized that the project had commercial potential in 1976-1977 and used several different mechanisms to generate industry interest in the innovation.

He attended a major conference sponsored by the MIT Industrial Liaison Program (ILP) office at which he talked about the R&D projects going on at the BECCI. This generated some interest in possible collaborative agreements with several of the participants and one in particular, but no transfer agreements materialized. The one firm that was most interested reorganized and the talks

never resumed.

Dr. Rogers also tried to make contacts at trade shows, but again, was unable to get any commitments.

The key contact, which was more the result of coincidence or luck than a specific strategy of the BECCI or firm that the project was transferred to, was made when one of the people who works at the center learned that his neighbor's company was interested in expanding its product line with some type of cardiac monitoring device. He arranged a meeting between Dr. Rogers and Jim Smith, an engineer for Life Line Systems, Inc. around the end of 1981 and the bedside arrhythmia project was out the door.

Life Line Systems, Inc is a small private firm which was started about 5 years ago. Prior to its involvement with the bedside arrhythmia monitor (BAM), it sold one product, the emergency response system. This is a communications system which allows users to signal a hospital when an emergency arises and they need help. The device activates and transmitts a prerecorded message over telephone lines to a central monitoring station where someone is dispatched in response to the person's call.

Sometime in the late 1970's or early 1980's, the company started searching for new product ideas to complement its orientation towards medical monitoring systems. In talking to a number of physicians and cardiologists about their needs in this regard, company personnel learned about the problems of monitoring patients

with cardiac arrhythmia disorders. Life Line became interested in developing an improved arrhythmia monitoring system and began developing plans when Smith learned about the work at MIT.

The transfer agreement is based on an exclusive collaboration arrangement between MIT, Beth Israel, and Life Line. Life Line is providing MIT with arrhythmia research grants for continued algorithm development in exchange for an agreement not to publish or provide detailed BAM technical data, schematic diagrams, or program listings to other firms without Life Line's permission. Since no patent was involved in the transfer, the basis for establishing some degree of proprietary protection is know-how. Life Line wants to keep potential competitors from having free access to such information.

The original funding for the project was provided primarily by NASA, so if there had been a patent, NASA would have owned it and all related technical information would have been freely available to whoever wanted it. When the NASA funding ended, MIT then controlled all subsequent research information and was able to make this transfer agreement with Life Line.

COMMERCIAL PROTOTYPE DEVELOPMENT

At Life Line, new product development occurs in 5 basic stages: functional definition; systems design;

hardware/software development; engineering and market testing; and prototype refinement, systems documentation, and production. As Smith explained, Life Line recognizes the importance of effective engineering, marketing, and user interface and both marketing and R&D are co-equally involved with product definiton, evaluation, and scheduling based on their own contacts with potential users. Smith conducted a series of interviews with a number of doctors and cardiologists at Beth Israel Hospital and used his previous work experiences involving medical devices in determining what changes needed to be made with the MIT prototype in order to commercialize it.

Although the MIT system was adopted essentially unchanged, the following modifications were made or are being made in the commercial model:

- Use of a better trend display device. The MIT model used a storage tube display that was of poor quality and flashed when changes were made.
- Use of a different family of logic cards because the company that provided them to MIT went out of business.
- Use of a printer that provides hard-copy records of ECG's and trend plots to improve system functionality. The MIT model printed ECG strips but did not provide a hard-copy trend plot unless an optional printer was used. Life Line redesigned the BAM to include a printer that could print whatever is shown on the CRT display screen.
- Simplification of the front panel controls to facilitate ease of use by targeted users who generally would not have the level of technological sophistication as the MIT users.
- Redesign of the front panel layout to provide a

a more attractive and less complex looking appearance. A Boston industrial design firm was hired to make these changes.

The MIT prototype used 16 buttons to control trend monitoring, quadrant, duration, and time increments. Life Line simplified the design to where only one button performs these same functions. The user simply presses it until the trend pattern he/she desires appears on the screen. A single print button then provides a hard-copy of the display. Similarly, minor changes in other functions and features such as simplification of alarm and display controls and the addition of a cover for the key board were also made.

The commercial prototype is expected to be finished by the summer of 1983. The company then plans to begin testing and to go commercial in November.

Before November, two additional tasks must be accomplished. First, the manufacturing process must be updated to comply with the good manufacturing requirements of the FDA and to handle the more sophisticated assembly requirements of the BAM. Second, the company must obtain FDA approval before it can sell the BAM commercially. They do not foresee any problems with either of these requiements and expect commercialization to go as planned.

From the time the relationship with MIT was started, about one and a half years elapsed in getting the BAM to its current state of development. About half of this period, 6-8 months, was spent in building up the firm's

in-house engineering staff to do the work. Life Line had to hire a group leader, two engineers with experience in electo-medical technologies, and a marketing product manager.

In addition to not having the necessary in-house talent to help in the planning, and development, the time expended in finding and hiring them put the project behind schedule by about half a year. Smith estimated that the one and a half year period could have been reduced to 4-6 months if these people had been on board from the beginning.

With respect to funding, the company is using its own money to finance the project. Cash outlays are allocated each quarter and have been slightly higher than anticipated but are within reason.

ORGANIZATIONAL RELATIONSHIPS

Smith initially assumed the role of project champion and was responsible for selling the proposal in-house. Although Life Line was looking for a new product idea such as the BAM, Smith recalled that generating project support was a relatively difficult process. The BAM was just right for the market need that the company had identified, but it was technologically, highly sophisticated for the company's limited resource base. Life Line wanted something a lot simpler and less risky. They knew that product evolution

would be slow and that they needed experience in a hospital setting, but they decided that there was a significant market for the BAM and accepted the project.

Several other factors influenced their decision to accept the project. First of all, several key people in the company had strong backgrounds in medical device technologies, including Smith and the manager of the sales department.

Second, they were able to arrange for an exclusive collaboration agreement with MIT without which, the agreement most likely would not have been accepted. Life Line feels that it has a head start over competitors because of this arrangement, but potential sales and expected returns on investment were not discussed.

Finially, MIT had developed its prototype just far enough down the road to commercialization for Life Line to see the feasibility in getting it to the market with a certain amount of risk and uncertainty. Smith said that they extended themselves to the limits of their capability in accepting this project. If MIT had done any less or if they had to do any more, the project would have been unacceptable.

CASE 2: BLOOD REJUVENATION SOLUTION

INVENTOR: Naval Blood Research Lab, Boston University School of Medicine.

FIRM: Pipa Labs, Inc.

INTRODUCTION

In the late 1960's, the Naval Blood Research Laboratory, a government-owned, contractor-operated facility now co-located with the Boston University School of Medicine, began work on improved techniques for the freeze-preservation of blood products. Over a 10 year period, they developed a biochemical solution that not only allowed outdated blood, that previously would have been thrown away, to be treated and restored to usable form, but also allowed further processing for long term preservation for at least 10 years. This solution was transferred to a start-up firm near Boston, Massachusetts which now produces and sells the product commercially.

BACKGROUND

The director of the Naval Blood Research Laboratory (NBRL) is a Professor of Medicine at the Boston University School of Medicine and a Navy Captain. Although the U.S. Navy funds most of the research done there, most of the researchers are university staff and graduate students usually on their way to medical school. The lab's mission

is to respond to Navy operational requirements by performing research and development and to transfer the results to industry for production of the needed equipment and software. The lab interfaces with local firms in order to get the desired new products manufactured. These firms benefit from having new products developed and tested and the lab benefits from the transfer of new technologies into the operational areas of the Navy.

In the latter part of the 1960's, the Navy began looking for ways to preserve blood for longer periods of time. They were shipping large quantities of blood to Vietnam during this period, but were experiencing considerable problems with outdating.

The Naval Blood Research laboratory solved this problem by developing a biochemical solution and process that allowed outdated blood to be treated and restored to usable form. Not only did such treated blood have acceptable post transfusion survival rates, which is 24 hours for fresh blood, but its oxygen carrying capacity was either restored to normal or improved by as much as 300 percent. The rejuvenation process can either be carried out before the blood becomes outdated or 2-3 days after the outdate period.

Another key aspect of the rejuvenation technique concerns the long term preservation of red blood cells. Rejuvenated blood that is not used within 24 hours of biochemical modification can be frozen with glycerol and

stored at -80 C for up to 10 years. After thawing, washing, and reconcentration, the blood is again good for use within 24 hours. Non-frozen, rejuvenated red cells must be washed before transfusion to remove the rejuvenation solution.

Blood banks and other organizations that must manage large inventories of blood, such as hospitals, the Red Cross, and the Navy, may benefit from the use of the rejuvenation innovation in several ways. Rejuvenation allows:

- -the cost effective recovery of outdated blood;
- -long term preservation of surplus and rare red blood cells;
- -more flexible, rational, and less wasteful management of blood inventories.

PRODUCT TECHNOLOGY

After collection from a donor, blood will deteriorate over time until it is therapeutically ineffective and must be thrown away. Various techniques have been attempted to restore such outdated blood to usable form.

The two biological measures of the effectiveness of red blood cells are the levels of adenosine triphosphate (ATP) and 2,3 diphosphiglycerate (2,3 DPG). The ATP level affects the post-transfusion survival of red cells. The 2,3 DPG level affects the ability of the blood to transport oxygen. Rejuvenation occurs when the ATP and 2,3 DPG

levels of the red blood cells are restored to normal levels or increased above normal.

From experiments, studies, and tests conducted at the NBRL various factors were found to affect the quality of rejuvenated, frozen red blood cells (i.e., the ATP and 2,3 DPG levels):

-the anticoagulant used during liquid storage;
-length of refrigerated liquid storage at 4 degrees celcius;
-hematocrit value of the blood cells during liquid storage;
-concentration and composition of the rejuvenation solution;
-composition and volume of the wash solution;
-length of post-rejuvenation storage at 4 C.

The type of anticoagulant used during liquid storage affects the shelf life of the blood. Several types which were tested during development of the rejuvenation process are:

-acid cirtate dextrose (ACD): 21 day shelf life;

-citrate phosphate dextrose (CPD): 21 day shelf life;

-CPD supplemented with adenine and glucose (CPDA-1): 35 day shelf life;

-CPDA-2: 35 day shelf life;

-CPDA-3: 35 day shelf life.

Depending on which anticoagulant is used, the 2,3 DPG level of red blood cells decreaes during the first 2 weeks of storage.

The hematocrit value of the cell concentrate affects the rate of ATP deterioration. If the value is greater than 90 percent, a significant decrease in the ATP level

occurs with prolonged storage at 4 C.

The chemical composition of the rejuvenation and wash solutions is, of course, the key factor affecting the quality of rejuvenated and preserved red cells. Several modifications in the formulas for the two solutions were made to arrive at an optimal chemical composition. For the rejuvenation solution, the following ingredients were used in the experiments: pyruvate, inosine, glucose, phosphate, and adenine. For the wash solution, various concentrations of sodium chloride, glucose, and phosphate were tested. Several of these chemicals are potentially toxic which is the reason the blood must be washed before transfusion.

PRODUCT DEVELOPMENT

In the late 1960's, the Naval Blood Research Lab was assigned the task of providing the Navy with some method of preserving blood for longer periods of time to prevent or reverse deterioration prior to use. This objective, as explained by the lab's director, required that he not only perform all the necessary basic research and studies to generate feasible solutions to the problem, but that he also completely develop and refine the product/process and produce it for Navy use. Since the lab has no production capabilities, this objective required that a manufacturer be found in the private sector to commercialize the product.

From 1968-1972, the lab was involved in some clinical studies of over 300 patients at the Chelsea Naval Hospital in Massachusetts. During this period, researchers learned about the role and importance of 2,3 DPG in maintaining the oxygen carrying capability of red blood cells. They experimented with various rejuvenation formulas, studied their effects in restoring ATP and 2,3 DPG levels, and developed the first rejuvenation solution, PIGPA.

Red cell concentrates with hematocrit values of 70 percent in ACD and CPD anticoagulants were stored for 22-35 days, biochemically treated with PIGPA, frozen for up to 2 years, thawed, washed, and tested after 24 hours of additional storage at 4 degrees celcius. The results of these tests were very promising. The oxygen transport function was found to be normal or improved and the 24 hour post-transfusion survival values were greater than 70 percent.

After more testing and modifications to improve the function and effectiveness of the solutions in rejuvenating the ATP and 2,3 DPG levels of the red blood cells, the NBRL developed three additional formulas: PIGPA solution A, PIGPA solution B, and PIPA Solution C.

These various formulas were tested against a similar solution developed by Fenwal Laboratories of Chicago and PIPA Solution C was found to have the best rejuvenation qualities. With the Pipa formula, indated and treated blood had a 200-300 percent increase in 2,3 DPG and a 175

percent increase in ATP. Outdated, rejuvenated red cells had a 150 percent increase in 2,3 DPG and a 175 percent increase in ATP. Outdated, frozen red cells were rejuvenated to normal or slightly improved levels. These results were achieved with CPD and CPDA-1 anticoagulants and with an hematocrit value of 80 percent.

The type of collection system used in the rejuvenation process was also a key factor in the development phase of this project. Others had said that rejuvenation was not safe because of the problem of contamination. They were concerned about the introduction of bacteria, spores, and other contaminants when the rejuvenation solution was added to the blood.

The NBRL director enlisted the help of a Bacteriologist at Tufts University who later started Pipa Labs to produce and market the rejuvenation solution, to study the question of what happens when an entry is made into a container of blood, such as with a needle or tube, with or without the addition of a chemical solution. They concluded from the studies that the rejuvenation process was safe and the risk of contamination from excessive handling of the blood was virtually eliminated. When they adopted a multi-bag system to replace the old system of glass collection bottles, several scientists also expressed concern about the plasticizers from the storage bags leaking into and contaminating the blood. Again, studies have shown that this is not a problem with these bags.

The multi-bag system consists of several polyvinylchloride (PVC) bags which permits the collection, component separation, liquid storage, freezing, and post thaw dilution of the red blood cells without ever having to expose the contents to the outside air. The storage bag did not have to be opened until pre-use washing was needed and this reduced exposure lessened the chances of accidental contamination of the contents.

The initial multi-bag system used a 600 ml primary storage bag. This bag was increased in volume to 800 ml to provide space for the anticoagulant to be added directly to the primary bag from one of the transfer packs. The 800 ml bag system not only decreased the risk of contamination, but facilitated use of the rejuvenation process and reduced user costs with respect to the old system.

In refining the cryopreservation (freezing) technique, two methods were tested: a high glycerol method using dry ice and a low glycerol method using liquid nitrogen. The former was selected because:

-the liquid nitrogen caused the storage bags to break, and

-dry ice is easier to handle than liquid nitrogen during the transport of large blood inventories.

The rejuvenation solution and the system were essentially ready for commercialization without further development when the product was transferred out of the lab. No changes were made in the chemical composition of

the rejuvenation formula and only a slight modification in the design of the cap to the bottle was made by the manufacturer to make it more compatible with other collection systems in use.

THE TRANSFER TO A FIRM

The NBRL director began this project with the intention of commercializing the blood rejuvenation concept. He, therefore, maintained frequent contact with industry and welcomed the interactions with senior managers who often used the lab as a source of new ideas and new products. The NBRL actively published all research findings not only for the sake of scientific knowledge but to also generate interest and increase competition among potential manufacturers. Competition leads to lower costs of final products and the NBRL wanted to get less expensive products on the market to minimize potential costs to the government.

As a matter of policy, the NBRL does not file for any patents or make any licensing agreements. The lab's director negotiates directly with companies himself to transfer whatever it is that he needs manufactured. These relationships, which include such companies as IBM, Millapore, Fenwal, and Haemonetics, are usually based on market potential for the new products. The firms are willing to invest in these projects on the basis of this

commercial potential and the good working relationship they have established with the NBRL.

In the late 1970's, the NBRL worked closely with a local firm to provide a supply of solutions for testing. To market the product, this firm only needed to get FDA approval for production and commercial sales. No additional product development or testing was needed since the NBRL had done it all. By 1981, however, they had not been able to meet the FDA's manufacturing requirements.

Before commercial sales of the solution can begin, the FDA has to approve the product and the manufacturing environment. The general procedure is to submit documentation about: the basic structure and organization of the lab; plans to make the product; manufacturing controls and techniques; batch testing results; and data from clinical tests. The manufacturing environment must be clean and procedures safe and reliable. The FDA conducts an on-site inspection to verify that all requirements have been met.

The NBRL director asked the Tufts Bacteriologist to look into the situation to see what the problem was. He found that the solution was being produced in a warehouse under highly unorganized and potentially unsanitary conditions. Good manufacturing practices were not being followed and often the work was unsupervised by the company's pharmacist. He also discovered that they were not following FDA testing procedures and were, in fact, not

in compliance with the government requirements. The firm eventually backed out of the project.

At this stage, the Bacteriologist had been involved with certain aspects of the project for several years and decided to take advantage of the situation by severing his ties with Tufts University and starting his own firm to commercialize the rejuvenation solution. Several factors prompted this move on his part.

First of all, due to personal reasons, he became interested in a job change.

Also, he was very familiar with the rejuvenation solution and process. He had helped the NBRL with some of the clinical testing and experimentation during the early development phase of the project and was familiar with the FDA approval requirements from his observations at the first company that tried to commercialize the solution.

Lastly, he believed the rejuvenation solution had a potentially large market. He never did any surveys but was aware of the potential value of the process to the Red Cross, hospitals, the Navy, and other large users through his association with the NBRL as the project progressed. Many doctors and researchers expressed interest and appreciation for the value of such a rejuvenation process which helped to substantiate his belief that a large market existed.

During the summer of 1981, the Bacteriologist got some money together, ordered the equipment he would need to

manufacture the solution, and started Pipa Labs. By February 1982, the first batch of Pipa Solution was produced. In April, he applied for FDA approval and received it in September 1982. The NBRL provided the bulk of the testing and experimentation data which greatly shortened this process. Commercial sales began immediately after the FDA gave its approval.

CASE 3: The Implantable Pump for Drug Delivery

INVENTOR: University of Minnesota

FIRM: Infusaid, Inc.

INTRODUCTION

In 1969, a student at the University of Minnesota was assigned as a summer project the task of finding a way to deliver the drug, heparin, to ambulatory patients with blood clotting disorders. Over the course of a year or so, a working prototype of an implantable pump for the continuous intravenous infusion of the drug had been developed.

Since then, a patent has been issued for the device, an exclusive licensing agreement has been arranged with a Massachusetts firm, FDA approval for commercial sales has been granted, and commercialization of the pump has begun, almost 10-11 years later.

MEDICAL HISTORY

The pump itself, is a totally implantable drug infusion device that delivers drugs directly to specific, localized sites in the body at a continuous, steady rate.

Many drugs are much more therapeutically effective if they are delivered into the bloodstream in this manner. A

patient who takes drugs orally or is administered drugs at regular intervals has a high concentration immediately after the drug is administered which decreases as a function of the half-life until the next dose when the concentration again reaches its peak level. This produces a sinusoidal effect and often results in potentially serious problems for many patients. For some, high levels of a drug can often be too toxic and low levels may not do the job intended by the physician, so an intravenous, constant delivery rate system is desirable.

The traditional method of achieving a constant rate in the delivery of a drug has been the "IV" technique often used in hospitals. This is the familiar intravenous delivery system that uses a relatively cumbersome set-up of bottles, tubes, and connections and that restricts the patient to a facility with the proper equipment.

To free the patient from such a restrictive and inconvenient therapy, several groups of scientists have been working on ways to deliver drugs from devices implanted in the body. Such devices would allow the patient to live a more normal life, but would also have the therapeutic advantage of constant-rate drug delivery.

One of the earliest such devices, which was first tried in the 1930's, is the pellet. This is the simplist kind of implantable drug delivery device and was designed to be implanted directly into the patient's tissue. The bodily fluids react with the pellet and cause it to

dissolve at a rate determined by the exposed surface area and solubility of the drug.

In the 1960's, experiments with small silicone-rubber reservoirs were conducted. The devices were implanted under the skin and the drug diffused through the rubber and into the patient's body.

A different, but similar device was developed with a selfsealing membrane that could withstand repeated punctures by a hypodermic needle. This allowed doctors to refill or remove medicine after the device had been implanted.

A number of problems still remained unsolved with these early devices: only drugs with low molecular weights could be used that would diffuse through a rubber membrane; the drugs could only be delivered to the surrounding tissue and not directly into the patient's blood stream as is often desirable; the drug delivery rate could not be adjusted or stopped after the device had been implanted; and problems with inflammation and rejection of the device by the body were common.

In 1969, work was started on the concept of the implantable pump by a team at the University of Minnesota School of Medicine that addressed all of these problems. Frank Johnson, an undergrad English major, started on this task as a summer project. The lab's director, Dr. Perry Downs was interested in finding a technique to deliver the anti-clotting drug, heparin, through continuous intravenous

infusion. The drug cannot be given orally and repeated injections tended to increase the risk of bleeding problems. Additionally, heparin molecules are rather large and many of the early devices could not be used.

By 1970-71, after about a year or so of research and development, the first prototype of the pump had been completed, the concept and design had been proven to be feasible through some preliminary animal studies, and a patent application was filed through the University of Minnesota patent office.

THE PRODUCT TECHNOLOGY

The pump is basically, a disc-shaped, titanium canister that is divided into two chambers by a diaphragm or bellows. The upper chamber contains the drug (infusate) that is administered to the patient and the lower chamber contains the vapor/liquid power source. The canister is filled with infusate by hand injection through the top of the canister. As the chamber fills, the bellows is forced down and compresses the vapor in the lower chamber. The compressed vapor, which is well above atmospheric pressure at normal body temperature, presses against the bellows at a constant rate and forces the infusate through a filter and flow regulator and into the patient's body.

One of the key concepts in the design of the pump is

the inexhaustible power source. The simple process of refilling the infusate chamber with more of the drug recharges the pump and prepares it for another cycle.

Another key feature in the design of the pump is the diaphragm separating the two chambers in the canister. The material used to make this feature had to be impermeable to keep the propellant from diffusing into the infusate chamber and contaminating the drug and dissipating the power source. Rubber or plastic could not be used for this reason, so titanium was selected over heavier steel. The diaphragm also had to be designed and installed so a constant pressure versus stroke ratio would be maintained in the pump.

THE TRANSFER TO A FIRM

In the early 1970's, after the concept had proved to be feasible, the lab began running out of money for further developing and testing of the pump. The original research was paid for by Johnson's summer fellowship from the Minnesota Medical Foundation; the federal government also provided some funding specifically for the development of such a device; and the lab was operating off of an NIH grant, so there were resources available for general use.

In order to secure additional funding to continue the project, the university team decided to try to find a

sponsor in industry. Johnson recalled that it seemed obvious to everyone that the device had commercial potential, but he is the one who went out and tried to generate some interest in the industrial sector. When asked why he took on this responsiblity, he said: "... no one else offered... The university was happy to patent it, as long as they didn't have to do any work... I quite enjoyed it, but there was no industrial transfer or liaison office at that time..."

Initially, they tried to interest a local firm in sponsoring further research, development, and testing of the pump. They felt this was a good choice because the firm was currently a producer of implantable biomedical devices and they had a good relationship with the university.

The firm conducted a market survey by sending out a series of questionnaires to a sample of physicians that turned in some poor marks for the pump. Apparently, because the implantable pump concept was new, untested, and not widely heard of, not too many doctors were interested in using such a device. Additionally, the survey revealed that the pump would have to sell for less than $100 if they attempted to commercialize it. The current Infusaid model sells for $3000. The firm turned down the lab's request for sponsorship.

They also tried to interest another large firm in sponsoring the project, but were again turned down.

The breakthrough came when the sales representatives of the firm that was supplying the lab with the titanium bellows for the pump learned about their desire for a industry sponsor. The sales people told the Metal Bellows President, Richard Morris, about the situation, and he flew out to Minnesota to talk to the university team personally. He apparently liked what they had to say, because he agreed to fund further development and testing of the pump and to do some engineering work to move the project along in the company. Morris made this deal with Dr. Garrett, professor of surgery and project supervisor, on the basis of a handshake and they agreed that Metal Bellows would be given an exclusive licensing agreement if and when the patent was approved.

Metal Bellows is a private firm that was started in the 1950's to make metal bellows primarily for aerospace use. They were the only makers of titanium diaphragms in the country and supplied them to the lab for their initial work on the pump concept. The company, however, had no experience in making biomedical devices and was geographically far removed from the lab, being located in Massachusetts.

According to Marion Thomas, a project engineer for the pump since 1974, Richard Morris made the agreement with the university without having done any studies or surveys. Thomas said that Morris was either naive, the university people were very persuasive, or Morris showed a lot of

insight. Metal Bellows formed a subsidiary company in the late 1970's to specifically develop and market the product which is currently being sold under the subsidiary's name, Infusaid.

PRODUCT DEVELOPMENT

When Marion Thomas joined Metal Bellows in 1974 and took over the pump project as project engineer, the company had no full time people working on the device. Morris had hoped to start clinical trials by 1973 and commercialization by 1974, but when Thomas came on board, he observed that several changes to the university prototype had been poorly made and that the pump was not good enough to be used as intended. Only three part-time designers and technicians were working in facilities that were not adequate for the task at hand and had only done work on the shape of the canister, the functioning of the diaphragm, and the design of the inlet septum.

Thomas' first order of business was to upgrade the design and assembly facilities and procedures and to correct a number of functional problems with the pump so the first clinical tests could be started.

The initial Metal Bellows model was lighter and more stream-lined than the university prototype which was shaped like a "hockey puck". The problems that had to be corrected with it were:

- A leak in the inlet septum. This rubber attachment had to be self-sealing to allow refilling of the pump by repeated injections with a hypodermic needle.
- A leak in the outlet port, which is where the outlet catheter is attached to the infusate chamber.
- An improperly functioning bacterial filter which is intended to keep any emboli that may have been introduced into the device during refilling from entering the patient's blood stream.

Thomas also was concerned about user requirements and other features that needed to be considered in the design of the pump. He asked Dr. Garrett to do more surgical implants on animals to gain some additional insights and experience about the device. Thomas said that he felt Garrett resented being pushed into doing these studies and was reluctant to do so. He felt that the firm was infringing on his domain and did not do any such implants for about 9 months after the request. What they learned from these implants was:

- the pump had to be shaped and designed to keep any sharp edges from possibly injuring the patient;
- some means of securing the pump to the inside of the body needed to be added;
- the catheter needed to be better designed to prevent clogging of the tube by the infusate or by blood.

In investigating the problems with the clogging of the catheter, the cause was identified as one of poor

manufacturing and quality control, not of design. The catheter had a diameter of only .003-.004 inches, about the size of a human hair, so extra care had to be taken and exact adherence to manufacturing procedures and specifications was needed to prevent clogging. Thomas had to develop meticulous cleaning cycles, to filter fluids prior to use, and to use special ingredients like "IV" infusion grade water used by hospitals instead of the commercial grade distilled water that they previously used. Bactericidal agents were also added to many ingredients to help prevent bacterial growth on and in the device. This helped to prevent clogging of the catheter and rejection of the device by the body.

In fact, Thomas had to upgrade the assembly process for all the parts that were used in the pump. Special ingredients that met toxicity and biocompatability requirements were needed because the manufacturer of such medical devices is legally liable for the safety and proper mixing and functioning and the various ingredients. Thomas contracted other labs to do some of the development work, especially when something needed to be done which was out of the company's area of expertise, but most of these out-of-house labs would not guarantee nor assume liability for the safety of their components. Thomas, therefore, had to buy many of the ingredients himself that met FDA food grade and food content specifications and tested, mixed, and made the components in-house.

Thomas also designed and set-up a special manufacturing process to clean and sterilize the components, ingredients, and the product in general. In all, about a year was needed to upgrade the equipment, facilities, techniques, and procedures which was completed by the spring of 1975.

By this time, the pump was ready for the first clinical tests with humans, but several problems arose. The first was that the university, where the tests were going to be conducted, had trouble finding patients. They initially thought there would be a large market for the pump, but that never turned out to be true. People with clotting disorders that needed treatment through the continuous internal infusion of heparin were hard to find.

Also, when they were ready to start testing, a world-wide heparin shortage occurred. Heparin, which is usually made from beef lungs or pork belly, could not be found in large amounts. The university team was eventually able to find a Canadian firm that could supply them with the drug, but only after the FDA approved the new supplier. The first human implants did not occur until October 1975.

By 1977, after nearly 2 years of testing with about 16 patients, the pump was proven to be reliable and functional. During this period, numerous incremental design changes were made to the device, which were all incorporated into a new pump protoype:

- the optimal pump shape and size was accepted;
- suture loops were added to secure the device inside the patient's body;
- the outlet port was redesigned to withstand sterilization;
- the outer metal surface of the pump was polished to prevent bacterial growth on the outside of the device and to improve its appearance;
- a white rubber sleeve was added around the sides and edges of the pump to provide a smoother and safer surface and also to give it a more attractive appearance. They tried and rejected a complete coating with silicone-rubber and a complete coating with the white rubber material. These made the pump larger than it needed to be and were rejected.

The university team determined that the key design criteria for the pump was the infusate flow rate. Unless the drug could be delivered at the proper dosage, the pump was of little value to the patient. The infusion rate for a given pump model was based on the physical size of the components and was structurally fixed. It could not be altered without redesigning the pump to achieve the flow rate that a given patient required. To get around this problem, several different pump models were developed and inventoried.

Further attempts to refine the design and to come up with one optimal model size and flow rate led to the discovery that one pump model could be used for all patients by simply varying the concentration of the drug itself. The flow rate (units/day) is a function of the infusate concentration (units/ml), the dose (ml/day), the infusate viscosity, and physical characteristics of the

device. Instead of changing the pump design for each different patient requirement or keeping several different pump models on inventory, the simpler solution was to just change the infusate concentration. To facilitate this mathematical calculation for the physician, the company prepared a table that indicated appropriate concentrations for various dose rates for approved drugs.

In 1977-78, another change was made to the pump design. An auxiliary septum was added based on the work of Dr. Bill Sorenson of the University of Michigan with the cancer drug, FUDR. The auxiliary septum gives the physician direct access to the outlet catheter and allows augmenting or supplemental drugs to be administered to the part of the patient's body being treated by the primary infusate. For example, the doctor can inject radioactive spores through the auxiliary septum and trace the flow of infusate through the blood and into a cancerous liver. The physician can then determine if the infusate is going to the right place or if the catheter needs to be repositioned.

INTERORGANIZATIONAL RELATIONSHIPS

The relationship between Infusaid and Metal Bellows with the people at the University of Minnesota is and has been basically good. The R&D staff at Metal Bellows were mostly mechanical engineers and technicians

and often ran into problems beyond their capabilities to solve. They had to rely on resources and talents at the university, especially with respect to the therapeutic and medical features of the design and clinical testing. Outside firms were also consulted on an occasional basis as required. A firm near Boston, for example helped with the design of the bacterial filters.

Thomas also observed a bit of "tug-of-war" going on between the firm and university before clinical testing had been completed. Apparently, the company was concerned about the small market for the heparin device and wanted to expand clinical use of the pump to more schools and hospitals to familiarize the medical world with the product and concept. The university people, however, wanted to do just the opposite. They wanted to restrict use and testing of the device to only those schools and physicians that they, not the firm, selected. They were afraid of any possible failures before the device had been completely tested and perfected. They were concerned about their reputations and wanted to control all studies, papers, and other such publications. This conflict did not end until 1977-1978, when the device was proven to be safe and reliable.

Up until 1978, the company found it difficult to convince people that the implantable pump technique was a good medical concept, due partially to the problems with the universty mentioned above. The key to the widespread

acceptance of the technology and process by the medical profession is attributable to the efforts of Dr. Sorenson of the University of Michigan. Although he was not formally linked with the company, he believed the pump idea had merit and decided to champion its diffusion and acceptance into the medical world.

Several of the people involved in the project feel that Dr. Sorenson put his reputation on the line by supporting and promoting the implantable pump concept. The NIH had published a study which gave the concept bad marks. This study, however, was based on the use of a portable, external pump that used a catheter running into the patient's body. This set-up was awkward and resulted in many failures. The catheters twisted, crimped, kinked, pulled loose, pushed into patients veins, and generally did not improve the patient's treatment or lifestyle. Sorenson believed that an implantable pump solved these problems and conducted his own studies to support the Infusaid device. His backing and resolve were key to the widespread diffusion and acceptance of the device as a therapeutically effective product. Today, hundreds of organizations are using the device with good results and the technique is branching out into new areas.

In all, over 10-11 years and a lot of effort was needed to get the first pump to the market as a commercial product. Johnson said that he felt the company would not accept the project if they had to make the decision over

again. It took about 5 years from the first animal implant to the first human implant; it took over 5 years from the first human implant to FDA approval. The company did not receive FDA approval for commercial sale of heparin and FUDR pumps until 1982.

A former engineer for Metal Bellows, attributed part of this lengthy process to the inexperience of the firm in dealing with the FDA. He said that no one in the company was familiar with FDA procedures until 1978 when an expert was hired. The company now has one person to manage and coordinate FDA and other regulatory affairs.

He also suggested that 3 other factors possibly contributed to the slow development and commercialization of the pump: limited financial resources; limited manufacturing and technical talent; and the lack of support from internal management.

Currently, Infusaid is still working with the people from various universities in funding and supporting continuing R&D for the pump product line. These university links include:

- the University of Minnesota which is testing some new pumps;
- the University of Michigan which is testing the pump with FUDR;
- other unnamed universities which are working on product improvements and new applications;
- the inventor who is developing and testing the pump for the infusion of insulin.

CASE 4: The Reach Toothbrush

INVENTOR: Tufts University

FIRM: E.I. DuPont de Nemours & Co., Inc.
and Johnson & Johnson

INTRODUCTION

In the early 1970's, a DuPont research associate became interested in developing and marketing an improved home dental care instrument for their toiletries product line. He came across an article written by a Tufts University professor concerning the application of human factors engineering techniques to the design of dental tools, instruments, and workspace layouts which he thought could be applied to the development of his new product idea. He subsequently contacted the professor and established an association with him that eventually led to a patent and successful technology transfer for DuPont and the successful commercialization of the Reach Toothbrush by Johnson & Johnson.

BACKGROUND

In the early 1970's, DuPont consolidated its consumer and fabricated goods product lines into one consumer products division. They made bristled and injection molded consumer goods such as combs and brushes which were sold

through drug stores, 5 & 10 cent stores and other mass merchandizers. The production facility for the division was located in Leominster, Massachusetts where products were designed and manufactured. The new products strategy for the toiletries product lines was to focus on appearance and novelty, not functionality. Designers seldom considered user needs when deciding about specific design features such as the shape and length of brush handles or bristle patterns, but relied on imitation and response to competitor initiatives or the input of some of the technical staff. These products were priced for the low end of the market, bore little or no identification with brand names, and were only marginally profitable for the company.

When Amos Reynolds joined the division as a Research Associate about this time, he was assigned the task of generating some newness and creativity in the toiletries product line. He recognized the need for a more proactive approach to R&D and new product development from observing operations after joining the division. He began his assignment by studying patents and trade literature and after reviewing several American Dental Association journals, identified a potential winner. Dentists were concerned about the generally poor state of oral hygene and the ineffectiveness of dental products currently on the market. He, therefore, reasoned that a new product that could effectively provide a better way for people to clean

their teeth had significant commercial potential. Reynolds noticed that most of the patented toothbrush designs which were all supposedly better than earlier models had all been designed by dentists. He also observed a general lack of human factors engineering considerations in the designs. Few models included features that made the instrument comfortable, easy to use, more efficient, or incorporated any of the design considerations expressed by a Tufts University engineering professor in a paper he wrote about the design of dental work stations, tools, and instruments. Paul Dexter's methodology considered: the way people use, move, and hold devices; hand size; positioning of fingers; time-motion observations; sequence and steps in performing certain actions, and other related considerations.

Reynolds felt that this technique could be applied to the design of a better toothbrush and intuitively decided to pursue the matter and champion the development and commercialization of such a new product. Since he did not have the training and skills to do the work himself and neither did DuPont among its in-house R&D personnel, he decided to contact Dexter about the new toothbrush idea. Reynolds flew to Massachusetts, talked to the professor, and established a one year consulting agreement to study the feasibility of the proposal. From that point on, Dexter began his association with the Reach Toothbrush innovation which resulted in a patent and successful

technology transfer for DuPont and successful commercialization by Johnson and Johnson which bought the product from DuPont, introduced it to the market, and is currently managing its continued development and sales.

PRODUCT DEVELOPMENT

In all, about 4 years were needed to develop and translate the initial idea into a commercializable prototype. Dexter worked with a colleague, John Wambaugh, who is also an engineering professor at Tufts University and Jerry Cohen, a dentist.

In order to determine if an improved manual toothbrush could be designed, Dexter's team started their work in 1972, by doing a literature search to find out what information was already available on the topic. Using graduate students to help, they searched patents, dental studies and articles, and other related literature and discovered that there was a definite need for human factors research in this area. There was a general lack of usable information in the literature, but their efforts did reveal a need to focus on plaque removal and gum massage as design goals.

They next began a search to find a good location to conduct clinical and user studies and to gather their own data about consumer dental care habits, attitudes, and requirements. After considering several institutions,

Dexter made an agreement with the Dental Hygene School at Westbrook College in Portsmouth, Maine. This provided a relatively low cost, isolated site which suited DuPont who were concerned about maintaining secrecy about their research focus.

The design team developed and distributed a questionnaire to Portsmouth residents which revealed some specific dental concerns, such as the need to: focus on cleaning the inside surfaces of back teeth; make brushing easier; design bristles that do not damage gums or tooth enamel; design comfortable brushes with simple handles and full heads.

They also analyzed the geometry and specifications of existing toothbrush models and obtained detailed measurements of adult hands, mouths, and teeth. Using this information, the design team was able to begin converging on an optimal toothbrush size and shape, but still needed more information.

When about a year had passed, 8-12 months, Dexter reported to Reynolds about their progress and the feasibility of the project. They concluded that a better toothbrush could be designed and Reynolds took on the responsibility for selling the proposal in-house. He recalled that his boss had followed the feasibility studies all along and gave his support by going up the corporate ladder and obtaining the support and funding of top management. DuPont agreed to continue their relationship

with the Tufts University design team rather than attempting to bring in the necessary talent and resources to develop the new product themselves. DuPont engaged Dexter in another one year contract to continue his work and develop a new toothbrush that would be better in removing plaque than the two leading competitors, Oral-B and Pepsodent. He was given complete design flexibility to come up with any type of device that would give DuPont the competitive edge in creativity and performance.

Back at Westbrook College, a series of time-motion studies were conducted to determine: the amount of time people spend brushing all of their teeth and the time spent brushing particular teeth; stroke direction and force; brush manipulation; and bristle deformation.

Additionally, plaque removal studies were conducted to study the effects of brushing time and bristle diameter on plaque removal. The designers tested four different diameters of bristles with two different tuft densities and were able to determine the optimal bristle diameter for plaque removal.

Sometime around 1975 or 1976, two basic prototypes evolved out of a number of different concepts that were based on the results of these studies and tests. Designs that were considered, but rejected include: one which used a sponge instead of bristles; one with a mirror on the back similar to the instrument dentists use to inspect hard to see areas in a patient's mouth; and one with twisted

handles.

These two prototypes were similar to the final toothbrush design in that they both had:

- angled handles to conform to the 12 degree angle of the jaw to the center line of the head;
- the smallest possible, elongated neck consistent with stress/force requirements to facilitate brushing hard to reach areas of the mouth;
- longer handles that tapered toward the bottom end of the brush and were less fatiguing to use than traditional models; and
- common bristle diameters (except for the bi-level model's inner bristles which were larger and firmer to facilitate plaque removal).

They differed, however, in several other respects:

- one prototype had a bi-level head and the other did not;
- the bi-level head was rounded, the other one, rectangular;
- the bi-level head model used a densely packed, hexagonal configured bristle pattern and the other used a standard linear bristle pattern;
- the bi-level model had a slightly rounded handle and the other had a trapezoidal one;
- other variations in the shape of the thumb flairs and dimensions of some of the other toothbrush features.

These two prototypes were tested against the two leading competitor models and were both found to be better in plaque removal. After conducting further interviews with users, the best features of the two test models were combined into one final design configuration which became

the Reach Toothbrush. The design team had achieved the goal set by DuPont.

In addition to the common features of the two test models that were included in the final design, the following additional features characterize the commercial model:

- A bi-level, rounded head configuration with a hexagonal bristle pattern. The thinner, softer, and longer bristles are on the outside to clean and massage along the gumline; the thicker, shorter, and firmer bristles are on the inside of the bristle layout to clean the teeth.
- A thinner handle to allow the toothbrush to fit into standard bathroom toothbrush holders.
- A slightly shorter handle with a modified thumb flair to make the toothbrush easier to manipulate.

Because this model had such a small, compact head which required that the holes for the bristles be drilled very close together, the design team had to compromise with manufacturing and alter the optimal design by moving the holes slightly farther apart. Without this modification, they found that the toothbrush could not be reliably manufactured and that too many bristles fell out of the head.

Also, in order to reduce costs, they stopped making the toothbrush out of nylon, which is relatively expensive, and switched to a less expensive plastic.

INTERORGANIZATIONAL RELATIONSHIPS

Throughout the transfer, Reynolds acted as the main contact between DuPont and the design team at Tufts University. He communicated with them at least weekly either face-to-face or by letter, telephone, or through offical interim reports.

Reynolds recalled that his main concern was to keep the design team's work focused on developing a commercializable product, but this never became a problem. He considered the working relationship between the two organizations to be good. They communicated well, the project was always on track, and the project goals were successfully achieved. In fact, in clinical claims testing, the Reach Toothbrush was found to be better in total plaque removal than the leading competitor products on the market. It was also found to have staying power with respect to competitive imitations because of its effective design.

Reynolds feels that the 4 years required to develop the initial idea of a better toothbrush into a commercializable product was longer than necessary. Dexter and Wambaugh could only work part time on the project since they were both teaching at the university throughout the innovation period. The elapsed time was, therefore, much greater than the actual work-hours expended.

During the early part of the project when no one was

really sure of the final form of the design, the design team was left pretty much alone to develop the best feasible product possible. Their main contact with DuPont was through Reynolds. When the optimal prototype designs began emerging, however, direct interactions with other company stakeholders became quite important and complex. Manufacturing was being done in Leomister, Massachusetts; marketing was working out of Wilmington, Delaware; test marketing was being done in Chicago; clinical tests were being done in Maine; and the design team was in Medford, Ma. A tremendous amount of interactions and coordination was required to get the new product ready for market introduction.

Another factor that added to the complexity of the final push to commercialization of the new toothbrush concerned the FDA's announcement that medical devices would be regulated. They had not decided on the classifications of the various types of medical products and DuPont did not know what manufacturing, testing, and marketing requirements would be necessary to get the toothbrush out the door. Key decisions that needed to be made had to be delayed or made with an unnecessary level of uncertainty. As it turned out, the toothbrush was placed in the least regulated category, so DuPont was able to continue with its current plans without any significant changes.

TRANSFER TO JOHNSON & JOHNSON

In 1976-1977, before market tests had been completed in Chicago, corporate management decided to divest itself of the Reach Toothbrush. Reynolds was not involved in the decision and is not sure why the company decided to get rid of a potentially profitable product just when it was ready to be introduced in the market and when test marketing was going quite well. He believes that the decision was strategic and reflected DuPont's desire to get out of the consumer products business which it did subsequent to its sale of the toothbrush to Johnson & Johnson in 1976-1977. Others, however, have expressed their beliefs that DuPont got rid of it because of their lack of marketing skills and knowledge.

The transfer to Johnson & Johnson took about 6-9 months. They bought the Reach patent, technology documentation, and studies for a fixed percentage of sales for a 10 year period, but the exact terms of the agreement are not known for sure.

Johnson & Johnson was concerned about a number of issues before introducing Reach nationally:

- validity of DuPont test data,
- manufacturing of the product,
- nature of the technology,
- marketing, and

- packaging.

DuPont sold the Leominster facility to an entrepreneur who is producing the toothbrushes for Johnson & Johnson, retained Dexter's design team as consultants, and conducted their own tests to resolve the marketing and packaging issues. They went commercial with the Reach Toothbrush in 1976-1977 without making any changes in the final DuPont design, but have made some design changes since then:

- 1976/1977 - introduced model with softer bristles to satisfy a market need.
- 1978/1979 - introduced childrens models in response to a new market opportunity. Again, Dexter's team specifically designed the children's brushes in accordance with human factors engineering techniques and did not simply scale down the adult brush. They made models for two age groups, 2-5 and 6-12, and even consulted child psychologists from Harvard and Boston University to provide design information about children's brushing habits and attitudes.
- 1979/1980 - introduced the Reach Plus to satisfy a market demand for toothbrushes with a larger head. The compact head on the DuPont model had 5 row of bristles. This new model was made longer and narrower with only 4 rows.
- all models are also made in 6 different colors to appeal to the largest cross-section of consumer preferences.

CASE 5: Viral Inactivation Process

INVENTOR: Confidential

FIRM: Confidential

Note - Due to the sensitive nature of this case, the actual names of the inventor, the firm, the universities, and the actual virus that the process was developed to destroy are disguised. The description of the technology, the dates, and the interactions discussed in the case, however, have not been disguised and are based on the interviews with people who were involved with the innovation and transfer attempt.

INTRODUCTION

In the early 1970's, a graduate student who was simultaneously pursuing a Ph.D. in electrical engineering and an M.D. at a major university and medical school in the Boston area, discovered that applying an electrical current to a solution of methylene blue (a photo-sensitive dye) and molecular oxygen in the presence of visible light, would result in the rapid inactivation of certain viruses. In fact, this process resulted in a destruction rate of the exposed viruses in excess of 99 percent and was patented by the university in 1978.

Hoping to commercialize this process, a firm located off Massachusetts Route 128 with whom the inventor had done some thesis related work, developed a prototype of the device, but never tested, produced, or marketed it.

BACKGROUND

Photodynamic inactivation is a process that has been used since the early 1900's to destroy living micro-organisms such as bacteria and various animal viruses. Using photo-sensitive compounds, which absorb and react to light energy, early experiments applied the photodynamic process to various viruses with some degree of success.

Methylene blue is one such photosensitive dye that was used in these early viral inactivation experiments. Around the turn of the century, its bacteria killing properties were recognized. It was also used to cure headaches and to purify water.

Around 1970, the inventor became interested in applying the photodynamic process to a certain well known virus. He began experimenting with various dyes and other photo-sensitive compounds and in 1973, discovered that the simultaneous application of an electrical current, visible light, and methylene blue resulted in the rapid destruction of the virus.

The key to the discovery is in the use of electricity. In addition to using too much dye, the early photodynamic experiments used no electricity and achieved only a 60 percent inactivation rate.

By applying a controlled amount of electricity to a specific concentration of methylene blue in an illuminated

aerobic solution of the virus, a 99.99 percent inactivation rate was achieved.

The dye, light, and electricity cause an oxidation reaction to occur which produces the superoxide radical anion, which in turn produces hydrogen peroxide and the hydroxyl free radical. These last two by-products of the process are what destroy the virus and other similar organisms.

The inventor does not consider the process to be dangerous to humans. The amount of electricity required to produce the oxidation reaction is very small. Experimental results showed that a dose of .000001 coulombs started the inactivation which accelerated at .001 coulombs and ended at .1 coulombs where the virus was essentially destroyed.

Additionally, the process was found to not affect healthy body cells due to the presence of superoxide dimutase, a natural substance not found in infected parts of the body. Because this substance inhibits inactivation and infected cells do not contain any of it, only the parts of the body contaminated with the virus are affected by the photodynamic process.

TRANSFER TO A FIRM

The inventor himself realized the commercial potential and obvious market need for a device that would cure the problems caused by this virus.

In 1976, while working with a local medical instrumentation firm on a thesis project, he approached the firm's president about his inactivation process and negotiated a transfer agreement.

Although the firm's president had some connections with the university's Innovation Center, Associate's Program, and Polymer Processing Program, the university was not involved in the negotiations. The inventor recalled that they were unwilling and reluctant to provide any help in funding further research and development for the project or in supporting his search for an industrial sponsor and he had to do all the work himself. In fact, an undergrad who worked as the inventor's research assistant had to be paid out of the inventor's own pocket.

The agreement with the firm did not commit them to a full scale development program. The project was accepted only as a feasibilty and research program. The inventor was paid a fee to work on the project along with an electrical engineering colleague who was hired as a consultant. They were assigned a few technicians to construct the device and were funded out of the engineering department's budget.

PRODUCT DEVELOPMENT

Since they were initially interested in only the commercial and therapeutic feasibilty of the viral

inactivator, the firm wanted to get a prototype built and tested before committing themselves to full scale development of the device. The inventor had done some testing and treatment of patients with his process during this period at a local medical center, but not with the commercial prototype. Although they intended to market the device to hospitals, clinics, and physicians, no market surveys or user interactions were planned or conducted and no assumptions were made about how much time would be needed to get a commercial product to the market.

The director of product development, who was program director for the project, met with the design team and talked about how the project should progress. They discussed design procedures and requirements, committed resources, and discussed how testing should eventually be done.

Testing was a key milestone for the project. The firm needed a detailed, step-by-step protocol of how the clinical tests were to be done to present to various hospitals in order to get their permission and patients' permission to use an experimental device for actual treatment of humans. They agreed at this initial planning meeting that the inventor would write this protocol and that a teaching hospital affiliated with the medical school where the inventor was working on his medical degree, would be a suitable site.

A disagreement, however, arose because the inventor

wanted to do testing on animals before the process was used on people in order to work out all the medical issues concerning the design. For example, the firm suggested using copper contacts with the prototype, but the inventor knew that copper caused adverse reactions on some people and preferred a different material. It is not clear if this testing issue was resolved before the project was cancelled by the firm.

In all, about one year and $30,000-$100,000 were spent in designing and constructing a prototype that would embody the viral inactivation technology. The inventor envisioned a simple application device consisting of a bottle of dye, a few cotton-tipped applicator swabs, and a 9-volt battery; however, they developed what the firm wanted which was a highly sophisticated piece of hardware that included a power supply, current source, timing circuit, anion exchange membrane (electrode), and controls.

WHY THE TRANSFER FAILED

The photodynamic concept is simple and the design and construction of an applicator prototype was relatively easy in that the design team had to only extend existing technology without a large resource commitment to get the job done. The project was adequately funded and supported and an obvious market need existed for the device.

The problem that ultimately caused the company to drop the project about a year after it was started, however, is not too clear. In talking to three different people who were aware of or involved with the project, three different views were given.

According to the program director for the project, it was dropped because the planned clinical testing on outpatients never took place. He said that the inventor, for some unknown reason, never wrote the protocol that the hospitals required before clinical tests could be conducted. He recalled many conversations he had with the inventor, who always seemed to be enthusiastic and a great advocate of the device, about the need for the protocol. The inventor appeared to understand this requirement for testing and always expressed his intention to write the protocol, but he never did. The project was dropped after all the firm's attempts to get the protocol written, failed.

The project director believes that the inventor never fulfilled this commitment to the firm, because he was spread too thinly. He was working on a Ph.D. and an M.D. simultaneously, in addition to pursuing several other projects, such as the current project, at various other facilities.

On the other hand, the inventor denied the contention that the protocol was not written and that he was working too hard. In fact, he presented a file copy of a testing

AD-A128 233 THE COMMERCIALIZATION OF NEW TECHNOLOGIES TRANSFER FROM LABORATORY TO FIRM(U) ARMY MILITARY PERSONNEL CENTER ALEXANDRIA VA H D JONES 09 MAY 83 2/2

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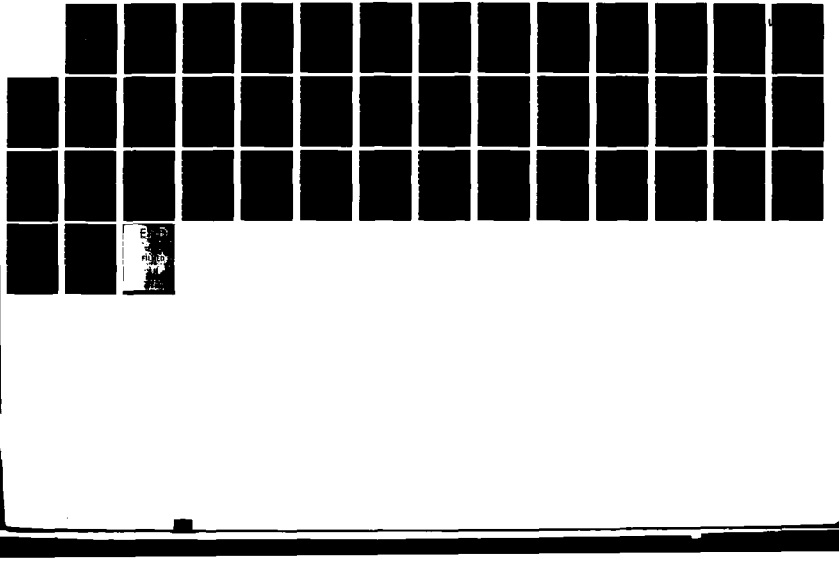

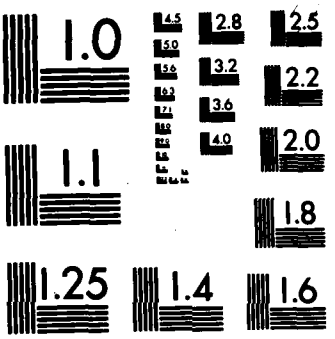

MICROCOPY RESOLUTION TEST CHART
NATIONAL BUREAU OF STANDARDS-1963-A

protocol and several copies of correspondance between himself, company managers, and officials at the proposed testing facility. Each of the documents that he presented had routing sections on the cover sheets that listed the names of the people that were intended to read them. It is curious that for each of these documents, including the protocol, the routing only went as far as the vice president. The president of the firm never lined through his name on the routing sections of the cover pages as the other people had done.

According to the inventor, the president told him that the legal time and effort required to obtain FDA approval for testing of the device were sufficiently prohibitive to warrant cancelling the project. A company lawyer was sent to Washington to talk directly with the FDA about the technology. He reported that their concern was with the use of any photo-sensitive dyes on people. Some dyes bind to human DNA and were possibly linked to cancer. As a consequence, the use of such drugs was prohibited.

In response to the assertion that the firm had problems with the FDA, the director of product development explained that the firm's product and technology focus is and has been on medical products and devices. They approach their FDA related requirements in a professional manner and are themselves, concerned about patient and operator safety regarding all the products they produce. The firm had an established protocol for commercializing

FDA regulated innovations which was disrupted when they could not get a clinical testing protocol from the inventor of the viral inactivation process.

The final viewpoint presented concerning the question of why the transfer failed was given by a university colleague of the inventor who is an inventor in his own right. He suggested that personality problems, internal politics, and jealousies, were the causes. The fact that a graduate student was hired by the firm's president and given the resources and support of experienced engineers and technicians to develop an out-of-house, yet prestigious new product was in itself reason enough to create serious internal problems in the firm. These internal conflicts were allegedly sufficiently disrupting to justify the cancelling of the project.

According to the program director, the company considered the hiring of another physician or consultant to write the protocol to be inappropriate. His opinion was that the writer needed to have:

- an in-depth understanding of the technology and the physiological implications of the process, and
- enough confidence and enthusiasm about the device to win the approval of the hospital review boards and patients to test it.

Since the inventor was the best person qualified to do this, the program director recommended that the project be cancelled.

THE STORY CONTINUES

Subsequent to the cancellation of the first transfer project, several significant events have occurred:

- the patent application filed by the university for the inactivation process was approved in 1978;
- three additional companies have expressed interest in developing a viral inactivator device, one of which offered the inventor $2 million;
- the inventor is now considering starting his own company to commercialize his invention.

CHAPTER VI: ANALYSIS AND DISCUSSION OF CASES

In this chapter, the five technology transfer cases are analyzed with respect to the issue of technology maturity and the key observations and findings are discussed. To facilitate this process, all the relevant facts and characteristics that relate to this issue and its impact on the commercialization of new technologies have been summarized and tabulated in:

Table 2: Case Facts and Characteristics Matrix;
Appendix C: Case Milestones
Appendix D: Prototype Design Changes

Referring initially to Table 2, a brief explanation of its contents is presented and is followed by a discussion of the key observations concerning the technology maturity issue and its impact on technology transfer and innovation. Chapter VII summarizes the analysis of the cases and concludes with a presention of the implications of these observations.

Table 2 characterizes the cases along 15 relative dimensions coded A-M. Note that Case 2 is broken down into two parts, 2a and 2b, to differentiate the first and second transfers to the two firms discussed in the case.

Dimension A classifies the technology transfers as either a success or failure. Recalling from Chapter III that a success occurs when the new product is introduced in the market for the first time and a failure occurs when it does not progess that far, only two cases out of this

Table 2: Case Facts and Characteristics Matrix

	Case 1	Case 2a	Case 2b	Case 3	Case 4	Case 5
A	success	failure	success	success	success	failure
B	8 yrs	15 yrs	15 yrs	13 yrs	5 yrs	7 yrs
C	.63	.73-.80	.73-.80	.07	.80	failure
D	.25	.07-.13	.07	.77	.20	failure
E	.12	.13-.14	.13-.20	.16	0	failure
F	II	II	II	I	II	I
G	moderate	minor	minor	major	minor	major
Ha	marginal	marginal	adequate	marginal	marginal	marginal
Hb	marginal	marginal	adequate	marginal	marginal	marginal
Hc	adequate	adequate	adequate	marginal	adequate	adequate
I	insign.	sign.	insign.	marginal	insign.	insign.
J	insign.	insign.	insign.	sign.	insign.	sign.
Ka	yes	yes	yes	yes	yes	yes
Kb	yes	yes	yes	yes	yes	no
L	med	hi	hi	lo	hi	lo
M	match	match	match	no match	match	match

Case 1: Bedside Arrhythmia Monitor.
Case 2a: Blood Rejuvenation Solution (first transfer attempt.
Case 2b: Rejuvenation Solution (second transfer).
Case 3: Implantable Drug Infusion Pump.
Case 4: The Reach Toothbrush.
Case 5: Viral Inactivation Process.

A -Transfer (commercialization) success or failure;

B -Duration of innovation process (initial conception by university to market introduction or cancellation of project);
C -Amount of time consumed in university R&D before transfer (percent);
D -Amount of time consumed in commercialization activities after transfer (percent);
E -Lost time (noise) (percent);
F -Maturity of product/technology at time of transfer;
G -Extent of prototype changes made after transfer (see table 3);
H -Adequacy of firm's resources at time of transfer:
Ha o Personnel (know-how, experience, skills);
Hb o Equipment and facilities;
Hc o Financial;
I -Impact of FDA good manufacturing practices requirement on firm;
J -Impact of FDA clinical testing requirements on firm;
K -Continuation of university involvement, advice, and assistance after transfer:
Ka o Inventor or other expert;
Kb o University, medical center, or teaching hospital resources, facilities, and equipment;
L -Extent of market and user interface done by university before transfer;
M -Relationship of new technology to firm's technology orientation;

sample, 2a and 5, involved failures. The reasons for these unsuccessful transfer attempts will be examined later in this chapter.

Dimensions B, C, D, and E establish the relative timing scheme of the innovations and transfers (also see Appendix C). The overall lengths of the innovation processes, measured from the time of initial conception of an idea, recognition of need, or recognition of technical opportunity by the university to market introduction or cancellation of the project are indicated by dimension B

and range from 5 to 15 years. These commercialization times are broken down into three segments. The first, dimension C, indicates the percent of time, with respect to the base dimension (B), that the innovation remained in the university R&D lab undergoing technology and prototype development. It is measured from the start of the innovation process in the university lab until experimentation, testing, and prototype development were completed.

The second time segment, dimension D, picks up the innovation from the time of transfer when the firm committed itself to the commercialization of the technology and is measured to the point of market introduction or cancellation by the firm.

Since time is often consumed by the university design teams in searching for firms to commercialize their inventions which is not accounted for by dimensions B, C, or D, dimension E is used. Dimension E also accounts for any errors and noise in reconstructuring the timing scheme of the innovations.

Although the nature of the technologies must be considered, the times indicated by dimension C provide a relative measure of the maturity of the technologies and prototypes at the times of transfer. The higher the percentage of time spent in the university lab (C), the more mature the innovation is expected to be and the less

the firm has to accomplish in order to commercialize the technology. The opposite is also expected to hold.

On the other hand, the amount of time spent in the firms' R&D labs undergoing commercial development is a reflection of commercialization efficiency. The proportionate amount of time the firm has to commit to adaptive engineering and commercial development defines the riskiness, uncertainty, and resource cost of the project and is impacted by the skills, knowledge, experience, and capabilities of the firms' R&D personnel.

Dimension F provides a measure of how the universities used the R&D time they had available to them before the transfers and is based on the convention used by the Denver Research Institute as identifed in Chakrabarti & Rubenstein (1973). The maturity levels of the innovations as they emerged from the university labs at the time of transfer are classified as either I or II. The I indicates the lesser level of maturity where only concept feasibility is demonstrated in the university prior to transfer which leaves a significant amount of additional research and development to be done by the firms in order to commercialize the technologies. The II indicates the higher level of maturity. For a product to receive this classification, not only must concept feasibility have been demonstrated prior to transfer, but a prototype must also have been developed and successfully tested on humans. The

expected observation with respect to technology maturity is that the more mature technologies (level II) should be more efficiently commercialized and more likely to be successful than level I technologies.

If the transfer of more mature technologies actually reduces the time and resource commitment required of the firms, then dimension D is expected to be small for level II transfers with respect to dimension C.

Dimension G provides an assessment of the extent of the changes made to the university prototypes after they were transferred to a firm. Rankings are classified as either minor, moderate, or major and are based on the information summarized in Appendix D. The expectations with respect to this dimension are that the more extensive changes will be correlated with: dimension C, where the longer the university develops the innovation, the fewer the subsequent changes are expected to be; dimension D, where the longer the firm retains the innovation, the more changes it is expected to make; and dimension F, where the higher the maturity level, the fewer the subsequent changes are expected to be.

Dimensions Ha, Hb, and Hc provide an assessment of the adequacy of the firms' resources at the time of transfer. Ha applies to the human resources of know-how, experience, and skill; Hb applies to equipment and facilities; and Hc refers to the financial resources of the firms. Since the

maturity of the innovations impacts the extent of the resource commitment required, the expectation in this regard is that the firms' resource endowments will impact the efficiency (dimension D) and the outcome of the projects (dimension A).

Dimensions I-M provide interesting observations about the cases and explain or supplement some of the expectations and observed correlations associated with them.

Dimensions I and J reflect the impact on the firms of the FDA required practices and procedures. Classified as either significant or insignificant, adherence to these requirements were made easier for the firms if the universities accomplished a major share of the requirements during in-university prototype development and testing. FDA required testing is expected to have less of an impact on the firms that are involved with level II transfers since these innovations are tested by the universities before transfer. Good manufacturing practice requirements, dimension I, are expected to affect the time, resources, and effort, the firms' must expend in the commercialization stages.

Dimensions Ka and Kb indicate whether or not the university researchers, inventors, or experts continued to be involved in the commercialization of the new products after they had been transferred to a firm. Ka refers to

the inventor or other expert with respect to the specific new technology being transferred; Kb refers to the university facilities and associated medical centers and teaching hospitals where user-interface and clinicl testing may be conducted for the firm. With less mature innovations, continued university advice and assistance is expected to be more critical than for the more mature innovations. This is especially important when there is a shortage of key resources in the firm, such as: personnel with adequate technical knowledge and competence to be able to understand the new technologies and continue commercial development; personnel with adequate medical knowledge about the physiological effects of the new technologies; and medical and clinical facilities to conduct vital animal and human tests in accordance with FDA regulations.

Dimension L gives an indication of the extent of market and user interface done by the universities before the transfers. The more effectively this is done, the less adaptive engineering the firm will be required to do which should be reflected in dimensions C,D, F, and G, as a measure of technology maturity.

The final dimension, M, indicates the relationship of the new technology to the firm's strategic R&D and technology focus and is based on a comparison of the new technology to the firm's existing products and technological knowledge base. This is included in the

analysis to provide some insight into the effect dimension M has on project success or failure (A) and commercialization efficiency (D). The expectation is that if a firm is going to attempt to commercialize a technology that it knows little about, then it should do so with a relatively mature technology.

WHY TRANSFERS 2a and 5 FAILED

The initial observations that are made from the comparison of the cases concerns the reasons that transfers 2a and 5 failed and the others succeeded. The reasons are attributable to an inadequacy of: (1) human resources - people with the appropriate knowledge, skills, and commitment to make the transfers succeed; and (2) clinical test facilities. The firms could not or decided not to attempt to overcome these deficiencies and the projects were cancelled.

For case 2a, the managers and technical personnel apparently lacked the knowledge and know-how required to implement the good manufacturing practices required by the FDA to achieve product safety standards. Despite the fact that the university had worked with the firm for several years while producing solutions for clinical tests, management still was unable to get their production established in an effective and suitable manner to begin

FDA approved commercial sales. It is not clear if this failure was due to having an insufficient number of qualified personnel or if it was just a problem with planning and implementation; but, the first transfer attempt failed and the reason is attributable to a lack of know-how or attention of management.

For case 5, the firm had no one with a detailed knowledge and understanding of the technical process that the university discovered and had to rely on the inventor to develop and test a commercial prototype. Although, they had technicians and engineers who were familiar with the hardware technology, they needed someone with an understanding of the untested medical process and hired the inventor and a university colleague to provide the needed expertise.

Although it is not clear if the inventor stopped cooperating with the firm or if the firm's engineering staff stopped cooperating with the inventor, the fact that they did not have anyone to take his place as the new technology expert (and/or champion) is a likely reason for the project's cancellation.

Also, the firm's technical management apparently lacked the willingness to defend and prove the efficacy of the new technology to the FDA. Perhaps this is due to there being no product champion in the firm, a misunderstanding of FDA requirements, or an unwillingness

to commit the time and resources to get the job done, but again, it is not unreasonable to have expected management to push the project forward assuming the expected returns exceeded the expected costs of compliance with the FDA certification requirements.

The failure in case 5 also indicates that the continued cooperation, involvement, support, and assistance of the universities themselves is correlated with the success or failure of the transfers. All the firms generally had adequate facilities, equipment, know-how, and financial assets to build the hardware associated with the new technologies, but this adequacy of resources did not apply to clinical testing facilities (dimension Hb) and user interface. In every case, other than case 5, the firms had to rely on the universities, associated medical centers, and teaching hospitals, to perform these critical, clinical tests and to obtain necessary input for medical and clinical design features. In case 5, neither the inventor nor the firm had the support of these university resources and facilities and perhaps this is the reason the firm decided not to push for FDA approval of the new product and cancelled the project.

Except for 2b, the other cases also involved marginally inadequate resources, but all ended-up as successful transfers. What makes these outcomes different from the failures is that the initial deficiencies were

overcome.

In case 1, additional people had to be hired before commercial development could effectively be started. The firm estimated that the total amount of time consumed by the firm in commercializing the innovation could have been reduced to a third of its actual value if these people had been available initially. It should also be noted that outside consultants were used in the design of the commercial prototype.

In the second transfer attempt for case 2, the key personnel were familiar with the problems and mistakes of the first firm and how to avoid them and were able to get commercialization approval in a relatively quick and efficient manner.

For case 3, 2-3 years after the transfer, the firm's initial prototype was not too much better than the university model. It was not functional enough to be used in clinical tests with humans which is significant in that the firm's president had planned on commercializing by this time. Instead, an additional 10 years were required to get the innovation to the market. Likely causes of this tremendous delay are:

- Inadequate technical knowledge of R&D personnel. Most were mechanical engineers with little or no experience with medical technologies. They had problems with toxicity and biocompatability requirements; meticulous manufacturing processes and techniques to ensure the reliable functioning

of parts and a sanitary and sterile product. Not only did the firm have to rely on the university to provide assistance and design advice, but they had to call in outside consultants to provide assistance.

- Inadequate quantity of technical personnel. For the first 2-3 years of the project, no full time project team had been designated. All work had been done on a part time basis.

- Competition for resources due to other on-going projects in the firm.

In case 4, the firm again did not initially have the in-house personnel with the necessary skills and expertise to develop the new product idea as conceived. This is the reason they contracted the university design team to completely develop a commercializable prototype. The firm did not want to go through the effort and expense of acquiring the necessary people and resources to do so themselves. The university provided the know-how and facilities; the firm provided the money.

Also, in case 3, indications are that considerable time and effort was required to achieve compliance with the FDA requirements. The final commercial prototype was completed in 1978, but FDA approval was not received for commercialization until 1982. The company did not have anyone knowledgeable about FDA requirements until 1978, when an expert was hired. This delay in obtaining a specialist is significant in itself, considering the invasive nature of the product and the obvious high concern of the FDA for its safe and reliable functioning in human

patients.

RELATIONSHIP OF TECHNOLOGY MATURITY TO THE DURATION OF THE R&D PROCESS

The next set of observations that are made from a comparison of the cases concerns the relationship of innovation maturity to the amount of time the technologies and prototypes remained in the university R&D facilities. The expectation is that the higher the amount of time spent in the universities, the more mature the innovation is expected to be and the less time the firm is expected to have to expend in commercialization activities.

Examining table 2, dimensions C, D, and F, these expectations appear to hold. For level II innovations, dimension C ranges from 63 percent to 80 percent while level I is only 7 percent. Correspondingly, with respect to dimension D, the level II innovations range from 7 percent to 25 percent while the level I value is 77 percent.

What this shows is that there appears to be a direct correlation between the level of maturity and the amount of time the innovation remained in the university R&D labs. This means that if the university takes the time and goes through the effort to demonstrate concept feasibility, develop a functional prototype, and do the clinical

testing, this will be reflected in longer R&D times for the universities and shorter R&D times for the firms.

Only cases 3 and 5 were classified at level I. In case 3, the university only developed a crude working model of the product that was used in some animal experiments which established the feasibility of the technological concept. In case 5, no university prototype was developed. The process was demonstrated to be feasible on the basis of laboratory experimentation alone.

It should be noted at this time, that if FDA testing had been done before transfer in case 5, the probability of commercial success would more likely have been enhanced. The firm would not have had such an obstacle to overcome with the FDA as the case seems to indicate. Also for case 3, indications are that commercialization most likely would have occurred faster and more efficiently if this testing had been done before the transfer.

The remaining cases were all classified at level II. In each one, a functional prototype was developed and successfully tested on humans prior to transfers and because of this, the firms had much less to do in order to commercialize the innovations. Since clinical testing on humans is a necessary commercialization requirement imposed by the FDA, test results provided by the universities saved significant amounts of time, resources, and effort for the firms as did having technologically more advanced

prototypes to work with.

RELATIONSHIP BETWEEN TECHNOLOGY MATURITY, USER-INTERFACE, AND PROTOTYPE CHANGES

The third area of analysis conerns the relationship between technology maturity, user-interface, and prototype changes. Dimension L of table 2 gives an assessment of the extent of market and user interface done by the universities before the transfers. Appendix D summarizes the specific changes made to the prototypes for each of the cases. Comparing dimensions F, G, and L, in Table 2, prototype changes (G) appear to vary inversely with the extent of the user interface done by the universities (L) and inversely with the levels of maturity of the prototypes at the times of transfer (F).

Since prototype development and the nature of the clinical testing done by universities requires significant interface with potential users of the new products (doctors, hospital staffs, and patients), the extent of user interface conducted before technology transfer is a measure of innovation maturity and impacts the efficiency and the extent of the prototype changes the firm had to make in order to commercialize the innovations.

There are only two cases, 3 and 5, in which the

university failed to appreciably consider user requirements in prototype design and one case, case 1, in which these considerations may not have been fully implemented.

In case 1, indications are that user features were considered but not completely incorporated nto the university prototypes. Most of the design changes after transfer were based on user considerations of quality, ease-of-use, and functionality. As the company explained, most targeted users were not expected to have the same level of technical sophistication as the university designers and users and prototype changes were made accordingly. The university appears to have focused on using inexpensive components, being able to obtain hardware and software support and servicing, and building a prototype that would safely work as intended. The changes made to the prototype in case 1 are considered moderate in that they did not change the underlying technology or system design, but changed only superficial features.

For cases 3 and 5, however, a larger number of more extensive design changes were made due primarily to the fact that reliable and functional prototypes had not been developed in the universities and extensive user interface had not occurred. The university labs were initially more concerned with technical feasibility and project financing than with commercial considerations.

In the case 3 situation, the university lab ran out of

money before more development work could be done. They had to find a corporate sponsor to support continued work, so the transfer took place and the firm became involved before the university had a chance to perfect the prototype and test it more extensively.

In case 5, the university did not support the inventor, no prototype was developed, and user requirements were not and could not be applied. The inventor was again constrained by a lack of funds and the project was delayed until an industry sponsor was found and the transfer effected.

Because the universities did not do so in cases 3 and 5 and to a certain extent in case 1, the firms were required to build prototypes, interface with users, and develop them into functional, commercializable products that incorporated the needed user features to increase the probability of commercial success. This omission tended to create more development effort for the firms and is correlated with the number of changes that had to be made by the firms in order to market the new products and the levels of maturity of the innovations at the times of transfer.

OTHER OBSERVATIONS

Another observation about the efficiency of commercial product development involves the relationship of the new technologies to the firm's strategic R&D and technology focus. In all the cases, except for case 3, the technologies that were transferred from the universities matched the firms' strategic focuses. This chacteristic appeared to have no effect on the outcome of the transfers, but did have an effect on commercialization efficiency.

With respect to case 3, the firm ventured into medical technology for the first time. Their previous orientation had been directed towards mechanical devices for the aerospace industry. As previously discussed, they encountered considerable difficulty in commercializing the innovation, taking 13 years instead of the three the firm's president had initially expected. The firm did not have the experience and knowledge to draw upon that facilitated commercialization and 77 percent of the innovation time was consumed in the firm.

Urgency of need for a new product is a reflection of the firm's willingness to accept projects despite obvious barriers. In case 5, the firm did not urgently need the new product which may have been a contributing factor in its eventual cancellation given the other factors presented

in the case and discussed above. No other observations could be made about the other cases in this regard because of the lack of explicit information about the firms' motivations and strategies.

With respect to timing, there is no evidence that overinnovation or underinnovation occurred due to the innovations remaining in the university labs too long. In fact, the evidence as presented above, seems to indicate that the longer the university developed and tested the prototype, the better.

With respect to timing and commercial success, case investigations did not go beyond the initial market introduction of the new products and information concerning events beyond that point is not available.

CHAPTER VII: SUMMARY AND CONCLUSIONS

In the preceeding pages, material was presented that indicated that many more commercializable ideas originate in university laboratories than ever reach the market as product and process innovations and that less than half of all innovation projects started by firms ever reach technical completion. These failures are attributable, in part, to the lack of understanding of the technology transfer process and the factors that impact the successful transfer and commercialization of technologies by organizations.

The purpose of this thesis has, therefore, been to investigate factors that impact the successful transfer and commercialization of new technologies in order to gain a better understanding of the process and ways to increase the likelihood of research utilization.

The particular focus of the investigation is on the issue of technology maturity. Five cases of actual transfer situations that have occurred between university labs and firms in the greater Boston area were developed and analyzed with respect to this issue. All the cases concern transfers of medical products, but the resulting observations are generally applicable to a number of different industries.

Recalling that the objective of the investigation is to determine why relatively few ideas and technologies are

transferred out of the universities where thay originate and why the probability of successful commercialization of new technologies is relatively low, what was learned in this regard is summarized as follows:

- If concept feasibility, prototype development, and clinical testing are done in the university lab prior to transfer, then: (1) fewer prototype changes are required of the firm; (2) less time is required for technical solution and commercial development.
- If prototype development and clinical testing are not done in the university prior to the transfer, then: (1) relatively more prototype changes are required of the firm; (2) more time is required by the firm for technical solution and prototype development.
- The transfer of maturer technologies is correlated with: (1) longer relative durations of the in-university innovation stages; (2) shorter durations of the in-firm stages.
- Efficiency of commercial development by a firm is impacted by: (1) the extent of user interface prior to the transfer; (2) maturity level of the technology; (3) knowledge, skills, and competence of the firm's technical personnel; (4) relationship of the new technology to the firm's core technology; (5) extent of required prototype changes.
- Success or failure of the transfers is impacted by: (1) the firm's knowledge, ability, and willingness to implement FDA required practices and standards; (2) the continued assistance and cooperation of the university inventors and experts; (3) ability of the firm to overcome resource deficiencies by hiring additional technical personnel, using consultants, contracting external design teams, allocating more resouces to the project, and using university resources and test facilities.
- Project funding is a major constraint on the university's ability to develop maturer technologies and prototypes.
- Problems with over-development of a tech-

nology or prototype by universities are not factors in these cases.

These observations imply that if the interorganizational transfer and commercialization of technologies is desired, then certain factors should be considered because of their potential impact on the likelihood of a successful technology transfer and the outcome of the commercialization endeavor. These factors represent the major implications of this thesis and are concluded as follows:

- The technology source can increase the likelihood of a transfer by developing a technology as far down the road to commercialization as possible prior to the transfer. This includes doing the following: (1) demonstrating concept feasibility; (2) developing a functional prototype; (3) successfully conducting FDA -related clinical tests; (4) incorporating user requirements and features in the design of the prototype.

- The technology user can increase the likelihood and efficiency of a successful transfer by: (1) having an adequate technical and managerial staff of persons knowledgeable about the technology and FDA requirements; (2) accepting transfers of technologies that are compatible with the strategic focus of the organization; (3) accepting transfers of technologies that are relatively mature and within the firm's capability and willingness to manage.

- The technology source can favorably affect the efficiency and outcome of the transfer by continuing to provide assistance, advice, facilities, resources, and skills to the techology user.

- The technology source and potential technology

user must make a trade-off between technology maturity and the amount of time, resources, and effort they can each commit to the success of the innovation.

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APPENDIX A: LIST OF POTENTIAL CASES

1.	Skin Equivalent	MIT	Still in lab
2.	Artificial Skin	MIT	Still in lab
3.	Heparin Solution	MIT	Still in lab
4.	Hydrogels	BUMS	Still in lab
5.	Automatic Peptide Sequencer	BU	Used
6.	Prostaglandines	BUMS	Used
7.	Slow Release Polymer	CH/MIT	Used
8.	Recombinant DNA	Harvard	Firm would not talk
9.	Recombinant DNA	MIT	Firm would not talk
10.	Diagnostic Kit for Hepatitis	MGH	Firm would not talk
11.	Contract Research	Harvard/MIT	Used
12.	Drug Overdose Detector	BU	Not suitable
13.	Penicillin Assay	Tufts	Firm would not talk
14.	Equipment-Research Swap	Stanford	Not suitable
15.	Immunoassays	MIT	Firm would not talk
16.	Ultrasonics for Tumor Treatment	MIT	Firm would not talk
17.	Disorder Treatment by Chlorine	MIT/MGH	Principals not available
18.	Clinical Microbiology	MIT	Still in lab
19.	Viral Inactivation Process	Confid.	Used
20.	Blood Rejuvenation Solution	BUMS	Used
21.	Implantable Drug Infustion Pump	U.Minn.	Used
22.	Reach Toothbrush	Tufts	Used
23.	Bedside Arrhythmia Monitor	MIT	Used
24.	In Vivo Energy Transfer	BU	Not suitable
25.	Left Ventricular Assist Device	BU	Not Suitable
26.	Artificial Cornea	BU	Not suitable
27.	Cell Growth Solution for Vascular Grafts	BU	Searching for firm
28.	Kit & Assay for Infected Cells	CH/Harvard	Searching for firm
29.	Vaccine for B-Strep	BWH/Harvard	Still in lab
30.	Blood Gas Detector	MIT	Inventor would not talk
31.	Biological Cell Lines	MIT	Inventor would not talk
32.	Biological Cell Lines	MIT	Inventor would not talk
33.	Production of Proteins in Bacteria	Harvard	Inventor would not talk

BWH = Brighams Womens Hospital
BU = Boston University
BUMS = BU Medical School
CH = Childrens Hospital
U.Minn. = University of Minnesota

Appendix B: Questionnaire

A. Major research questions:

1. What formal and informal transfer mechanisms (e.g., personnel movement, assumption of certain roles, contractual agreements) characterize complete versus incomplete transfer situations?

2. In the development of the product, are the timing and nature of design inputs related to the relative success (completeness) of the transfer?

3. What characteristics of the recipient firm (e.g., resources, technology acquisition strategy) are related to successful and unsuccessful transfer situations?

B. The Questionnaire

1. Product design questions:

   a. What changes have occurred in the design as it has evolved?

   b. Who is responsible for each of these changes?

   c. What problem/need was the change intended to address? (Customer needs; manufacturing ease; manufacturing or end costs; technical superiority, etc.).

   d. What source provided the information needed to make the change? (Previous job experience; colleague; media; an inventor; problem solved on basis of own capabilities, etc).

   e. When was contact with the end users initiated?

   f. What form did product improvement, information from users take? (Formal research; informal conversations; how many users; extent of their involvement).

2. Management roles in the research and development:

   a. Who first saw the commercial potential for the

concept? (Did the idea have to compete with others in the lab for funding? If so, who secured that funding?)

b. Who originated contact between the inventor and potential commercializer?

c. Who was responsible for obtaining funding for the product development at each stage of the work?

d. Who provided contact with the end-user?

e. Who received the technology at the firm end? (How was it brought into the company?)

3. Cultural, organizational gaps to be crossed:

a. What are the differences in perception about:

1. potential value of the technology;

2. usual success/failure rate of this type of product on the market, i.e., the amount of risk involved;

3. end market for the technology;

4. amount of resources (money, personnel needed to bring the product into production and how far product is from production. Use scale of concept to production model).

b. How do the "cultures " of the organizations differ with respect to:

1. the environment for innovation (rewards for innovation; funding for development);

2. types of innovation which are rewarded;

3. incentives for innovation (how does your superior decide whether you are doing a good job or not);

4. types of knowledge (scientific vs. market) valued.

c. In the university laboratory, what precedents exist for entrepreneurs? (How many people have started their own businesses, made money from inventions, etc).

4. Technology acquisition strategies of the firm:

   a. Who made the decision to purchase this technology?

   b. Why did the firm acquire this technology?

   c. What information was used in making that decision? (e.g., market forecasts, etc.).

   d. Where else did the company seek the technology?

   e. How is the new product related to current product lines?

      1. In manufacturing (similar or dissimilar in production process);

      2. In markets (similar or dissimilar markets being served).

   f. In five years, what percentage of total sales are likely to be generated by this product (or product line)?

   g. What match was there between the firm's existing resources and needed ones? (New personnel; new equipment; new capital).

5. Contractual arrangements:

   a. When were patents filed?

   b. Is there a licensing agreement? How negotiated? What are the basic terms? (Publication; secrecy; royalties).

   c. Was there a go-between involved during negotiations? (University patent office; ILP; etc.).

   d. Who funded the original research? Has that funding source (e.g., if federal research funds) led to any complications in commercialization?

6. Nature of the recipient firm:

   a. Is the firm an innovator? Leader in the industry?

   b. How does the firm usually acquire their new products? (What percentage in house; what percentage from outside).

7. Government regulations:

   a. What kinds of mandated testing procedures are required to bring the product to market?

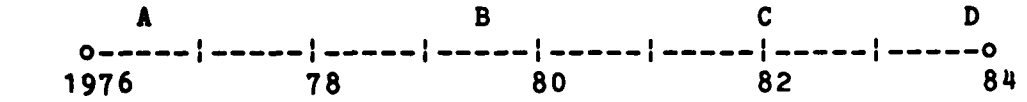
   b. Who is paying for that testing?

   c. What is the basic issue in the government regulation (safety, reliability, etc.)?

   d. Is there a stage at which the design must be frozen prior to introduction of this product? (When and why?)

Appendix C: Case Milestones

Case 1: Beside Arrhythmia Monitor



A - initial conception of idea, recognition of need, or recognition of technical opportunity by university, (76-77);

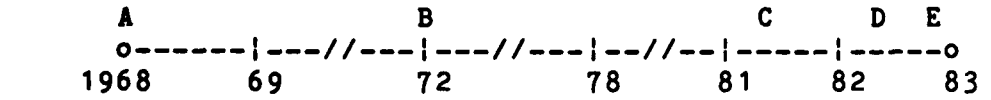
B - university prototype completed and clinical testing started, (79-80);

(B-C) - clinical tests;

C - transfer to firm, (Nov 81-Mar 82);

D - anticipated market introduction of commercial model, (Nov 83).

Case 2: Blood Rejuvenation Solution



A - initial recognition of need or technical opportunity by the university lab, (1968);

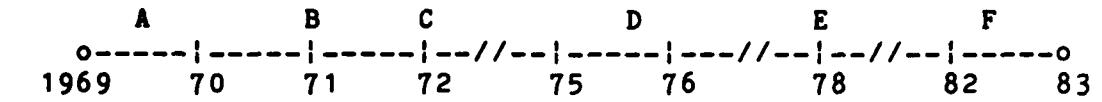
(B-C) - development of 3 prototypes of solution and multi-bag processing system;
failure of first transfer attempt, (72-81);

C - transfer to second firm, (summer 81);

D - application for FDA approval, (April 82);

E - FDA approval received and first commercial sales, (September 1982).

Case 3: Implantable Drug Infusion Pump



A - initial conception of idea and recognition of need by the university, (1969, summer);

B - university prototype completed and preliminary animal tests conducted, (69-70);

(B-C) - transfer to firm, (71-72);

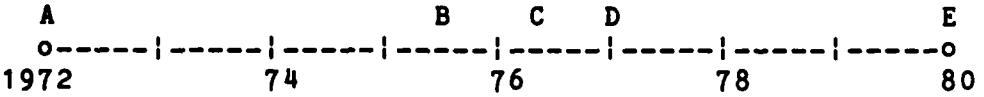
D - first human implants and testing, (Oct, 75);

E - final pump prototype completed, (77-78);

(E-F) - FDA requirements;

F - FDA approval and first commercial sales of pump, (1982).

Case 4: The Reach Toothbrush



A - initial recognition of need and technical opportunity by university, (around 1972);

(A-B) - series of studies conducted by university:

- o feasibility, (72-73),
- o consumer dental care habits and attitudes, (72-73),
- o time-motion, (73-75),
- o plaque removal, (73-75);

B - two toothbrush prototypes developed and tested, (75-76);

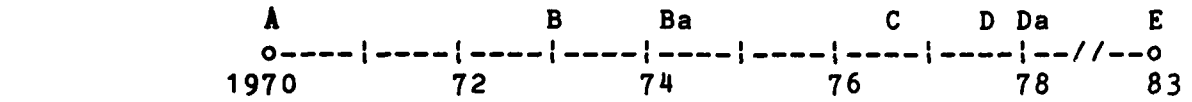
C - initial commercial model developed, (76-77);

(C-D) - transfer to firm; clinical and market tests started; sale of toothbrush to second firm, (76-77);

D - first commercial sale of initial model, (around 1977);

(D-E) - post-innovation product changes and improvements.

Case 5: Viral Inactivation Process



A - initial conception of idea and recognition of need of technical opportunity by university, (1970);

B - discovery of core technology for new product, (1973);

Ba - patent application filed by university;

C - transfer to firm (1976);

D - prototype completed (August 1977);

Da - project cancelled by firm (late 1977, early 1978); process patent approved (1978);

(D-E) - 3 additional firms seeking transfer agreement, (77-83).

Appendix D: Prototype Design Changes

This table outlines the changes made to the university prototypes after transfer to the firms.

Case 1: Bedside Arrhythmia Monitor

Date	Change	Reason
82-83	Redesign of CRT display device;	Improve quality of image; prevent flashing.
	Use of new logic cards;	Original supplier went out of business.
	Redesign of printer;	Improve functionality.
	Simplification of front panel controls and operation of device;	Improve user friendliness and ease-of-use.
	Redesign of front panel;	Improve appearance.

Case 2: Blood Rejuvenation Solution

A slight modification in the design of the cap to the bottle containing the solution was required to make it more compatible with certain user collection systems.

The rejuvenation solution, itself, was completely ready for commercialization when transferred from the university lab. No changes were made in the chemical composition of the formula.

Case 3: Implantable Drug Infusion Pump

Date	Change	Reason
72-74	Modification in size & shape;	Make pump lighter & more functional;
	Redesign of diaphragm;	Improve functioning;
	Redesign of inlet septum;	Prevent leaks;
74-75	Redesign of inlet septum;	Prevent leaks;
	Redesign of outlet port;	Prevent leaks;
	Redesign of bacterial filter;	Improve functioning;
	Redesign of size & shape; use of silicone rubber coating;	Remove sharp edges and improve functioning;
	Use of special materials & manufacturing and sterilization processes;	Prevent leaks & clogging of catheter; improve functioning;
75-77	Redesign of size & shape;	Improve functioning and ease-of-handling;
	Addition of suture loops;	Secure pump inside body;
	Redesign of outlet port;	Prevent leaks;
	Polishing of pump surface;	Prevent bacterial growth and improve appearance;
	Addition of rubber sleeve	Provide additional protection from pump edges; improve appearance;
77-78	Addition of auxiliary septum;	Improve functioning and diagnostic & therapeutic functioning.

Note: From 1971 to 78, over 10 different prototypes were

developed. The differences in these various models were either minor, represented incremental attempts to correct a given problem, or could not be recalled by the company personnel who were interviewed. This table associates these identified changes with the time period during which the company placed special emphasis on solving them.

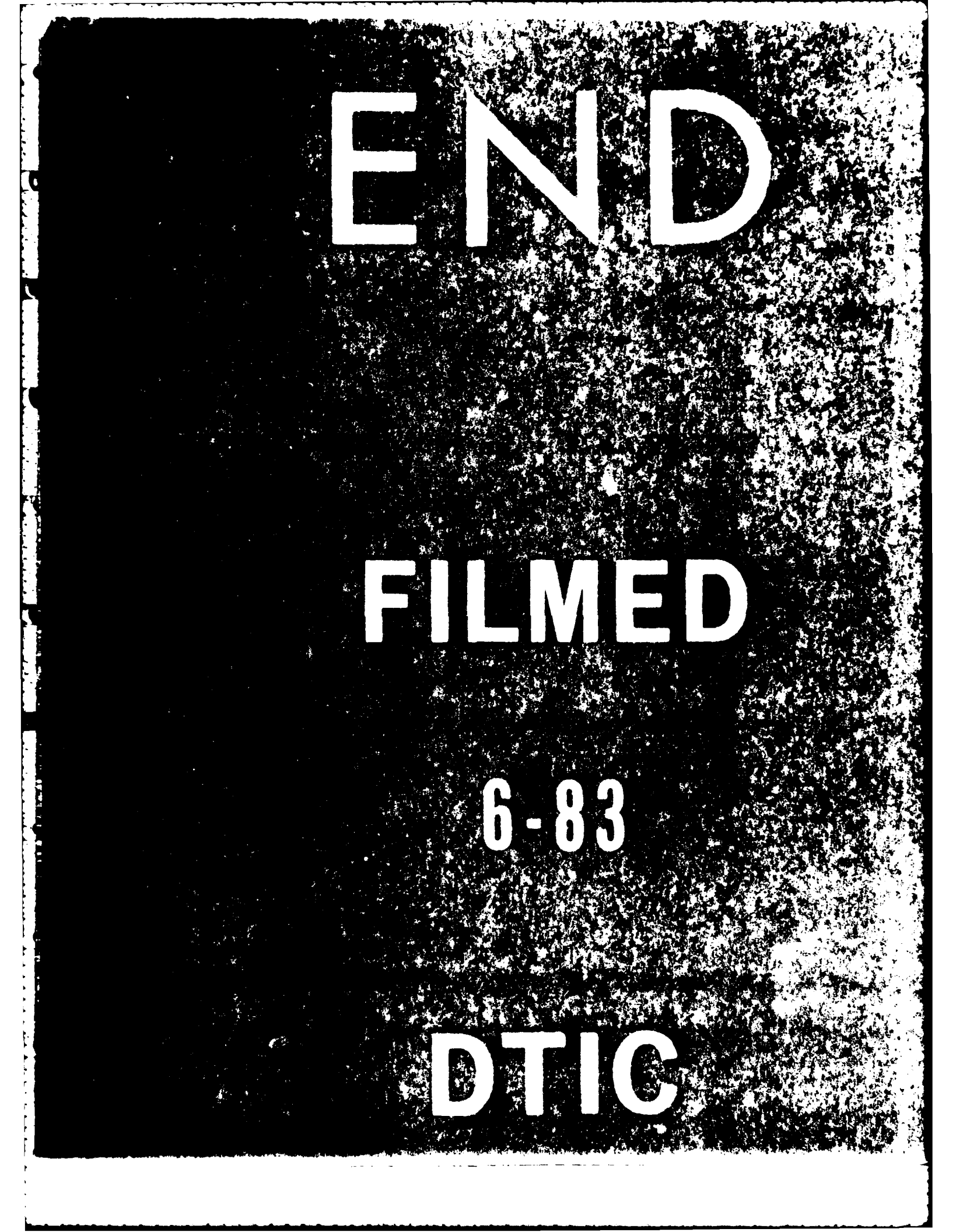
Case 4: The Reach Toothbrush

Date	Change	Reason
76-77	Switch from nylon to plastic;	Reduce costs;
	Toothbrush head slightly enlarged;	Facilitate ease and quality of manufacturing;
*76-77	New model developed with softer bristles;	Consumer preference;
*78-79	New childrens models developed;	Expansion of product line;
*79-80	New model developed with larger head;	Consumer preference.

* These changes were made after market introduction of the initial commercial model.

Case 5: Viral Inactivation Process

From 1976-77, the firm developed the first prototype of the device because one had not been developed in the university lab prior to transfer. A power supply, current source, timing circuit, electrodes, and controls were designed in this initial embodiment of the technology.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